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Fallin et al.

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(54) **FLEXIBLE BONE SCREW**

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(58) **Field of Classification Search**

CPC .. A61B 17/7208; A61B 17/7283; A61B 17/80

See application file for complete search history.

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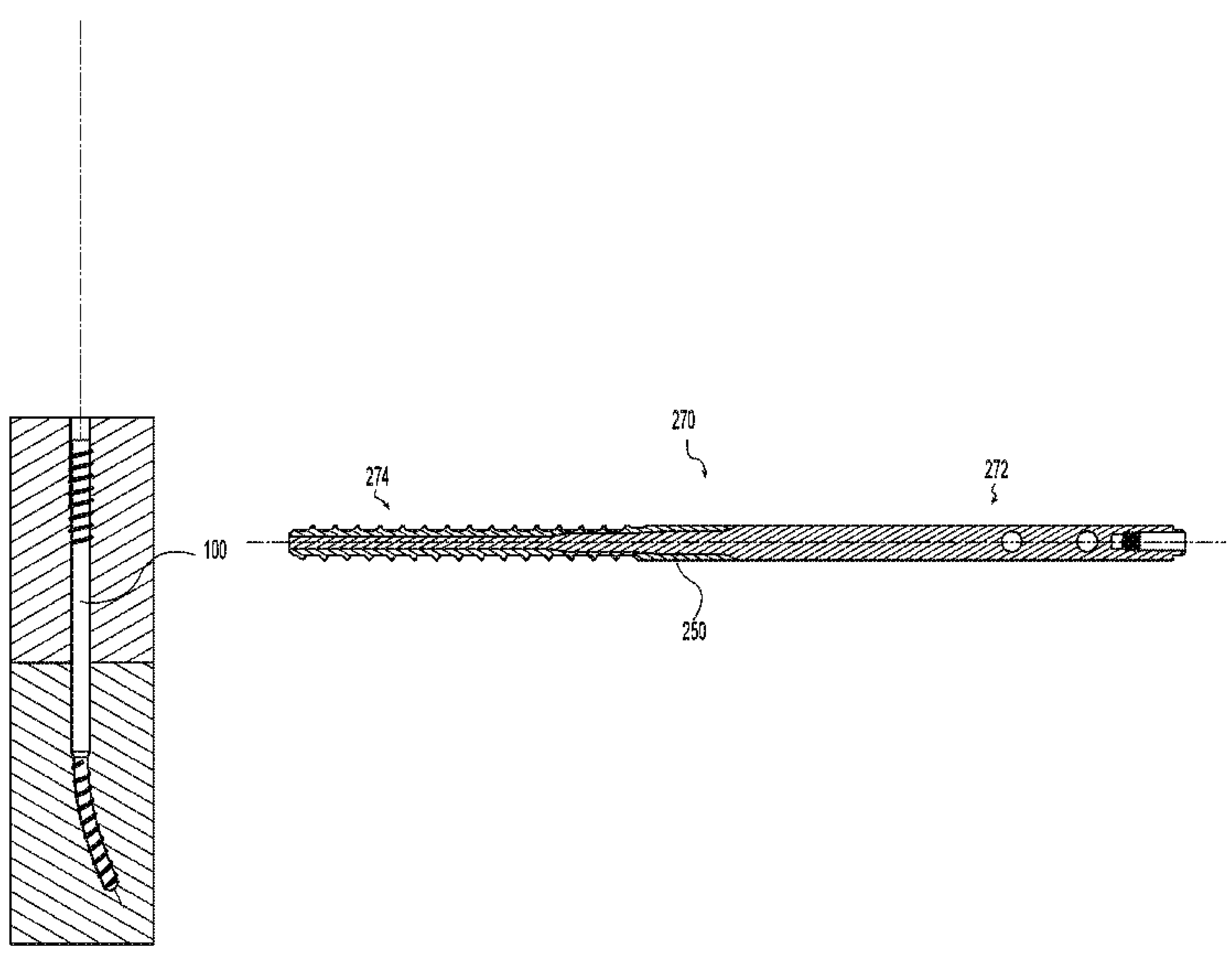
(57) **ABSTRACT**

Examples of devices and methods for stabilizing a fracture in a bone include a body having an elongate distal portion having an outer surface defining a screw thread and an elongate proximal portion having a non-threaded outer surface. In one example, a passage is formed through the proximal portion transverse to the longitudinal axis from a first opening on the surface of the proximal portion to a second opening on the surface of the proximal portion.

21 Claims, 16 Drawing Sheets



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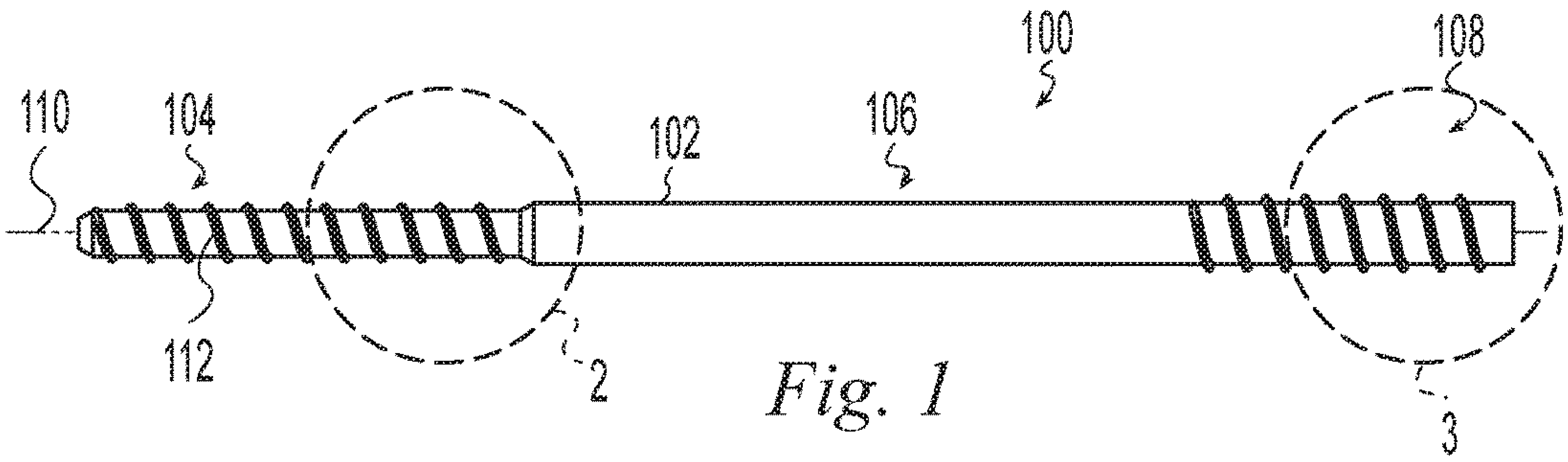
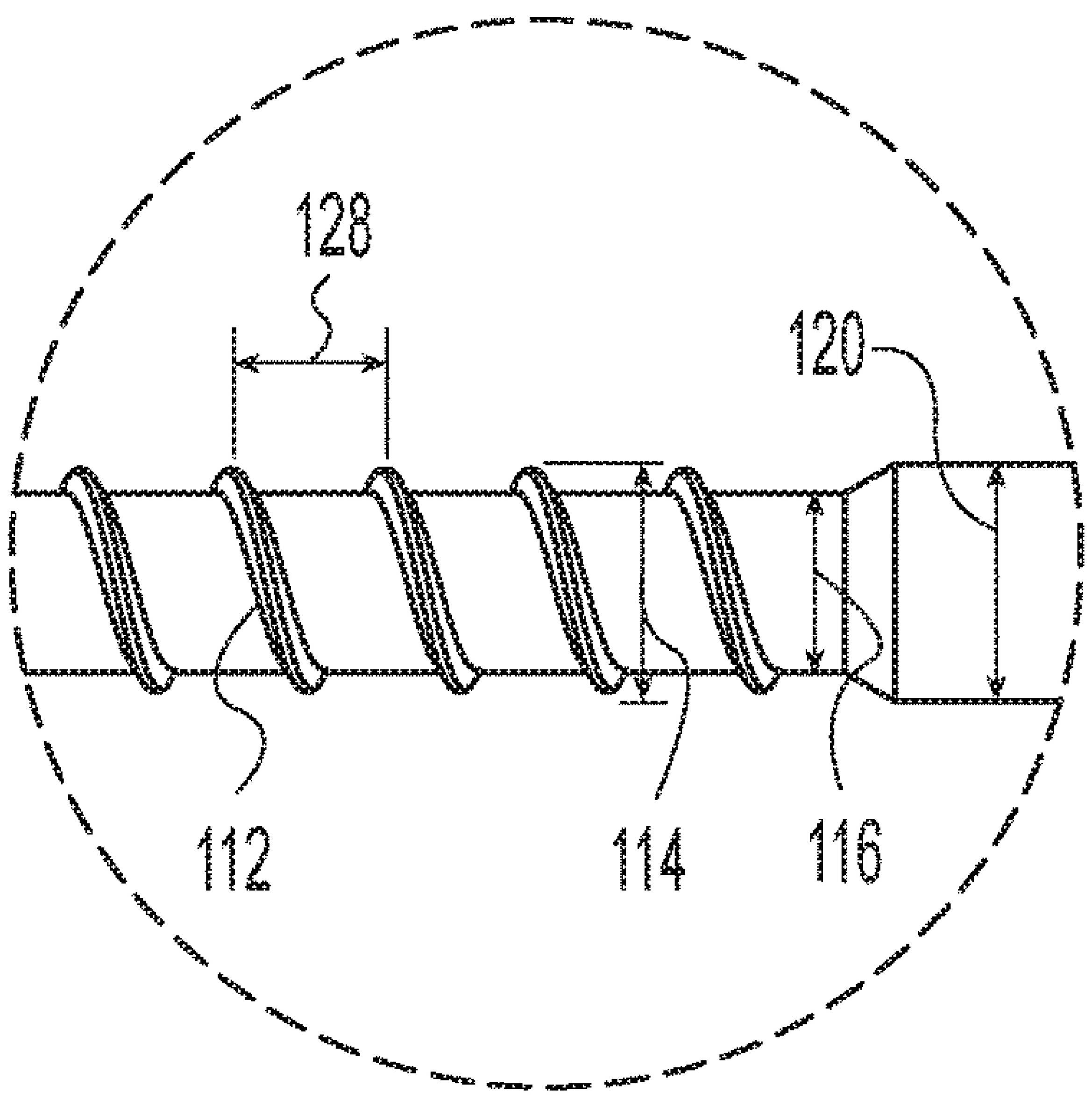


Fig. 1



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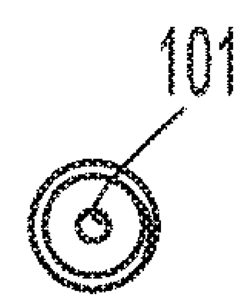

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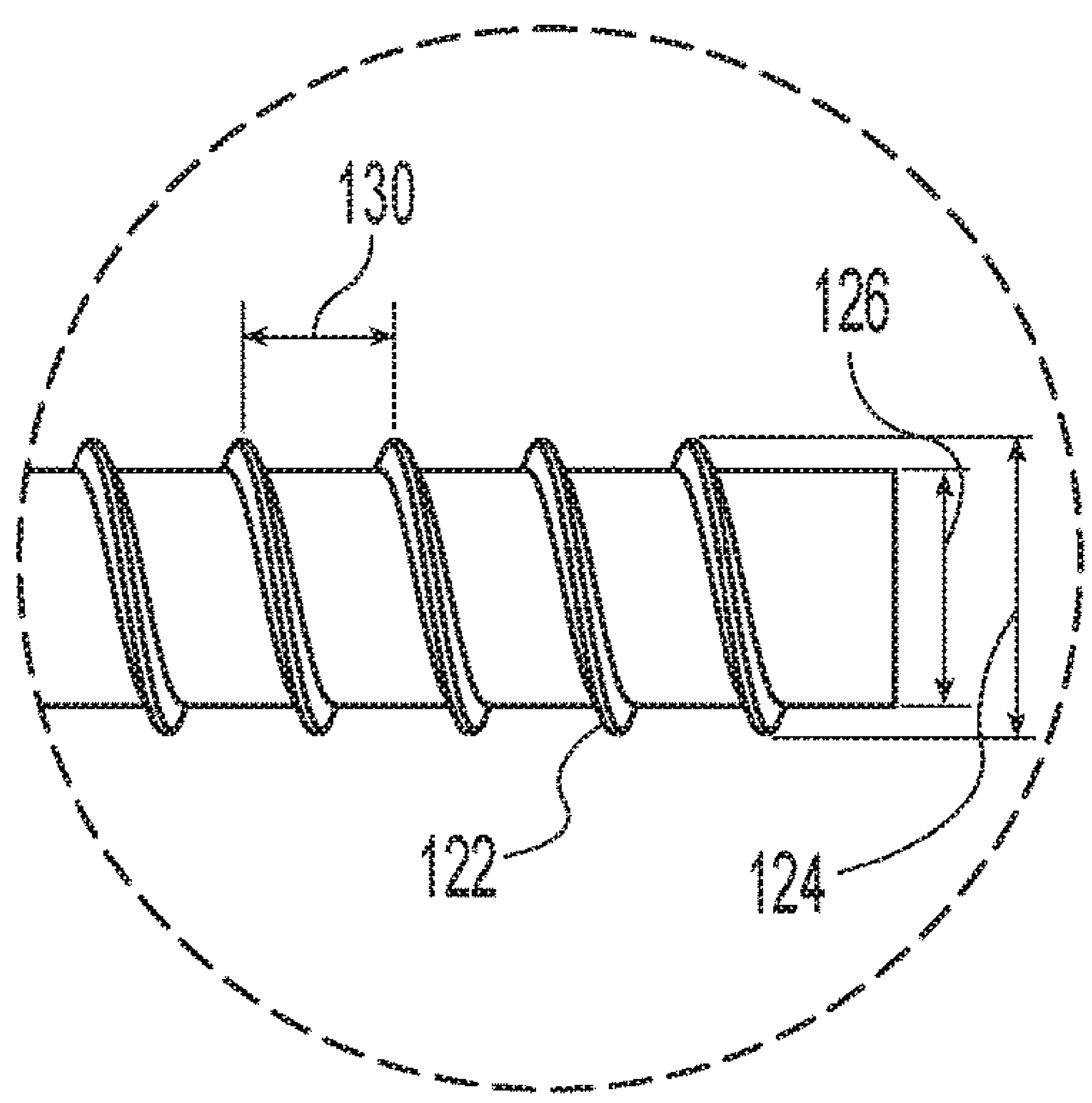

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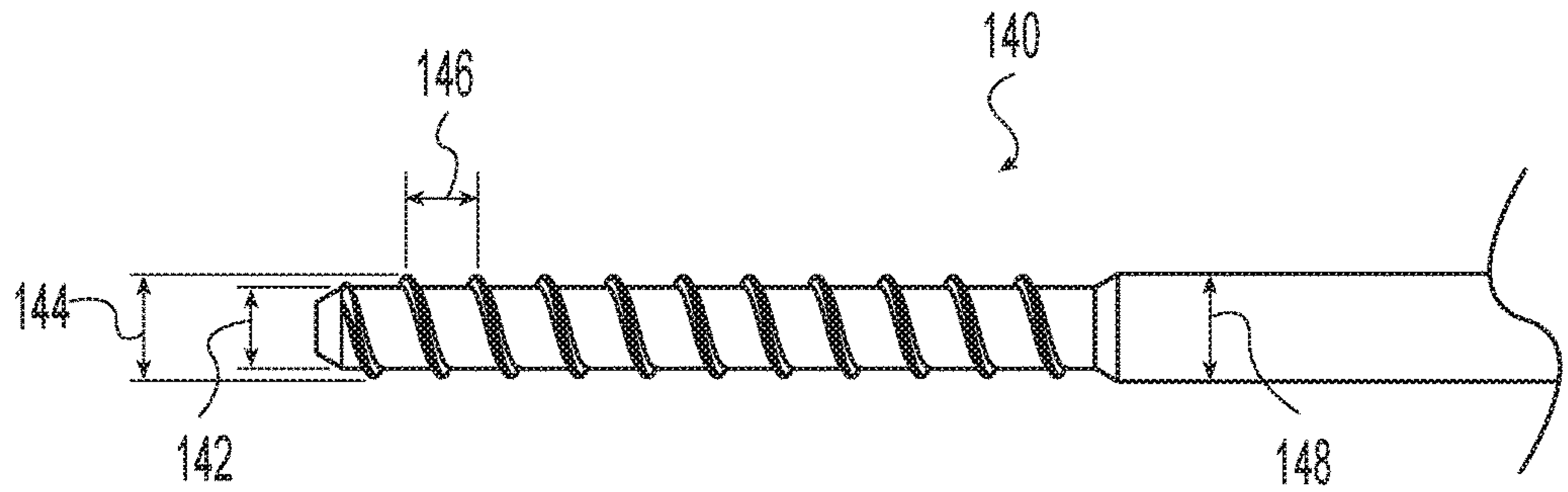

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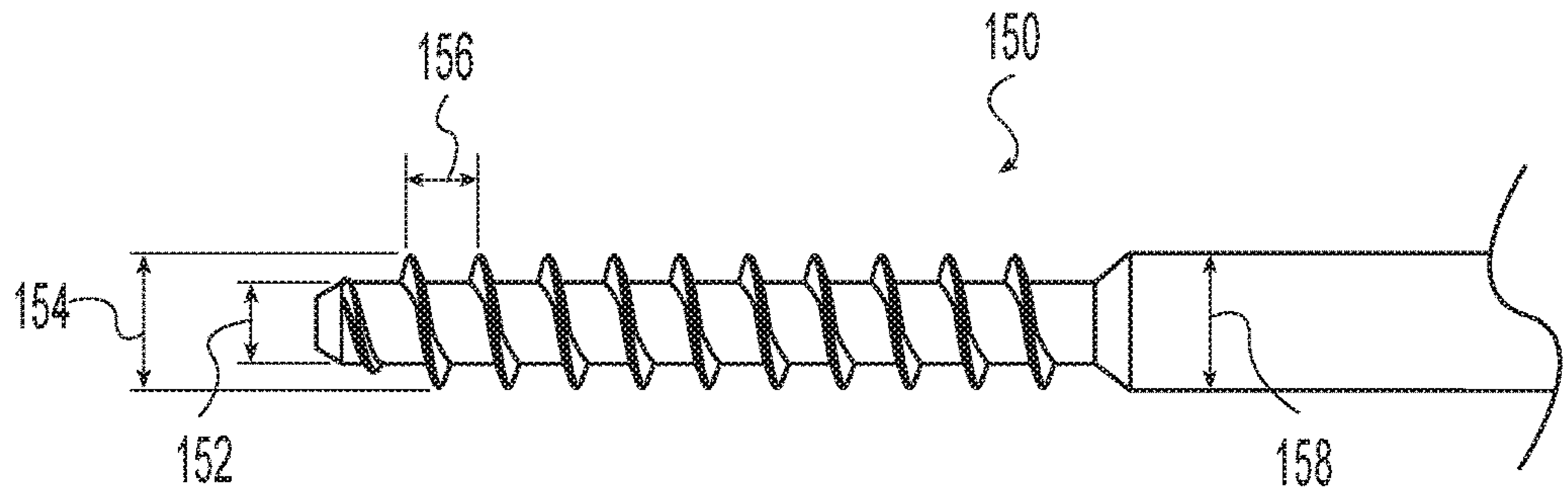

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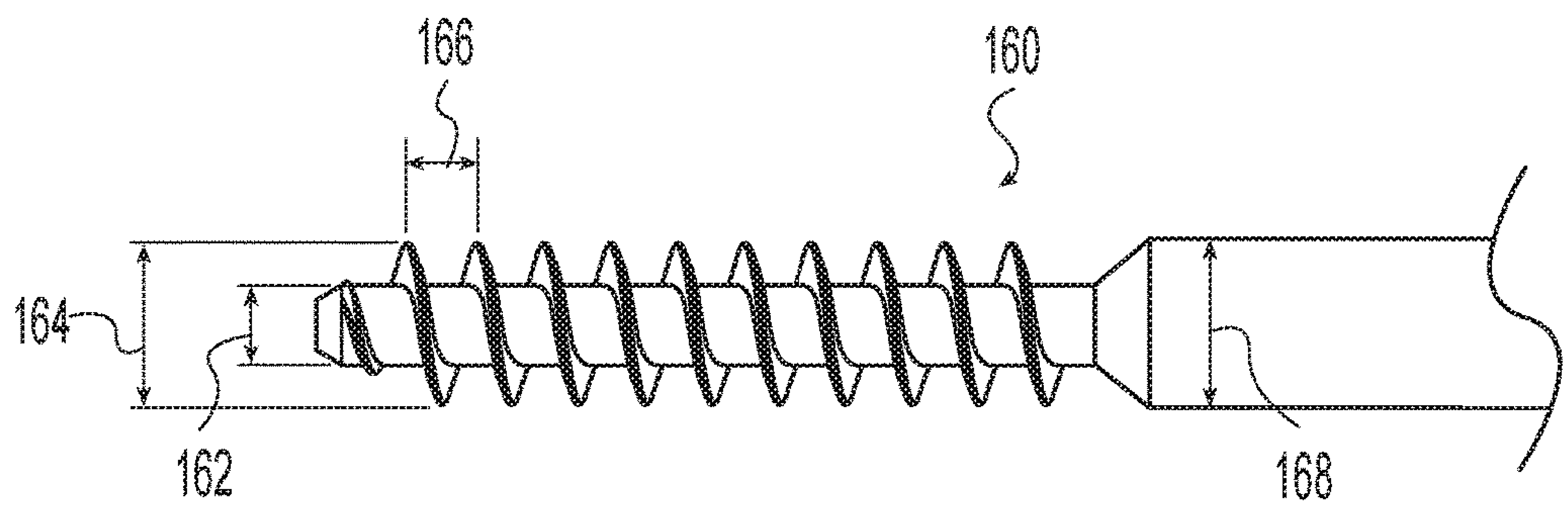

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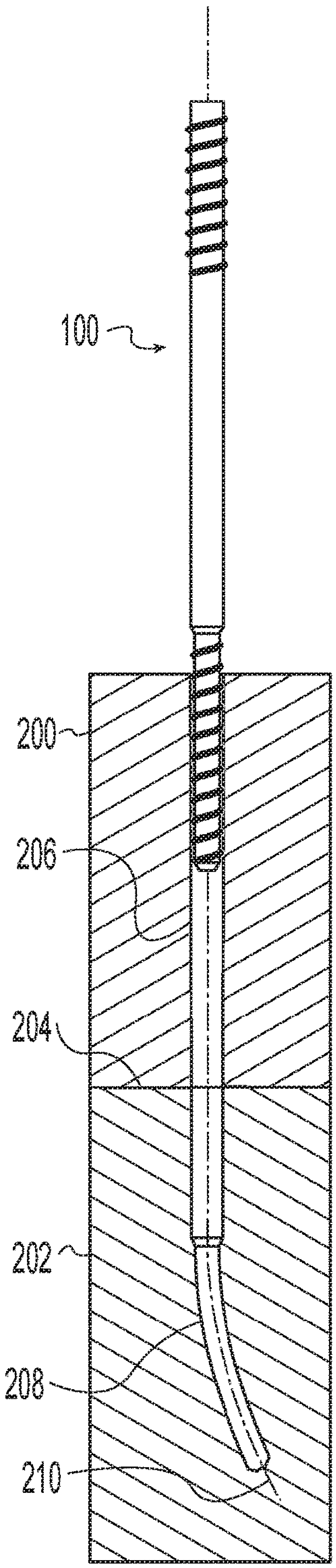

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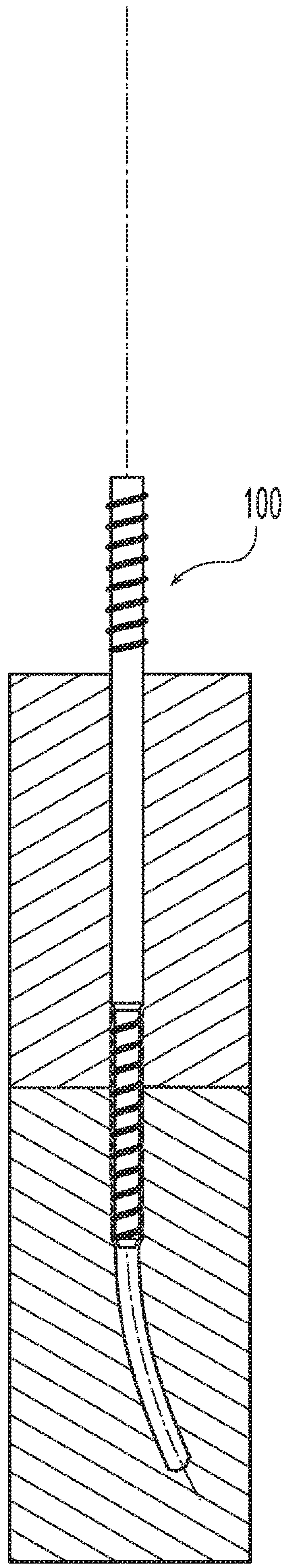

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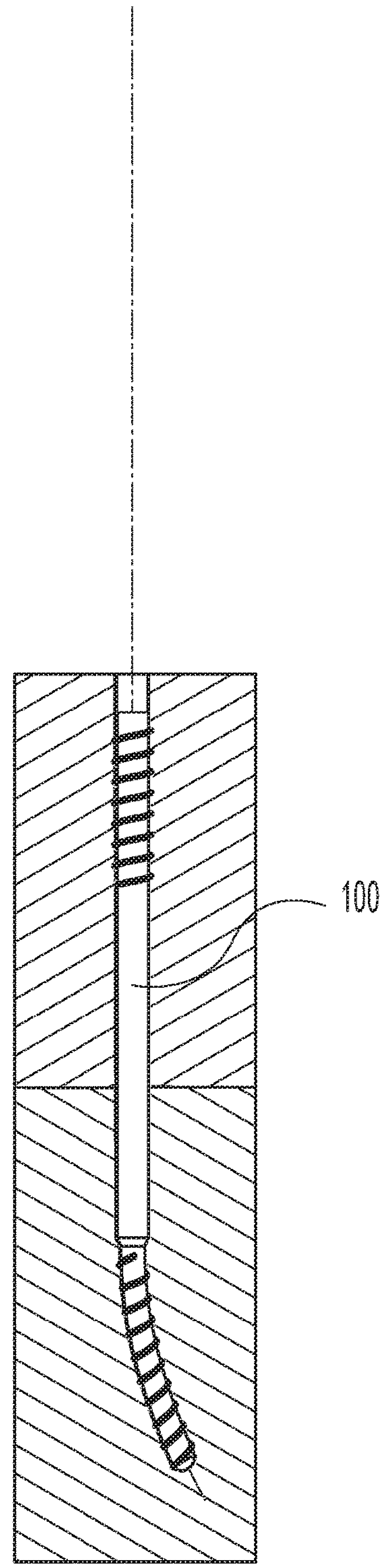

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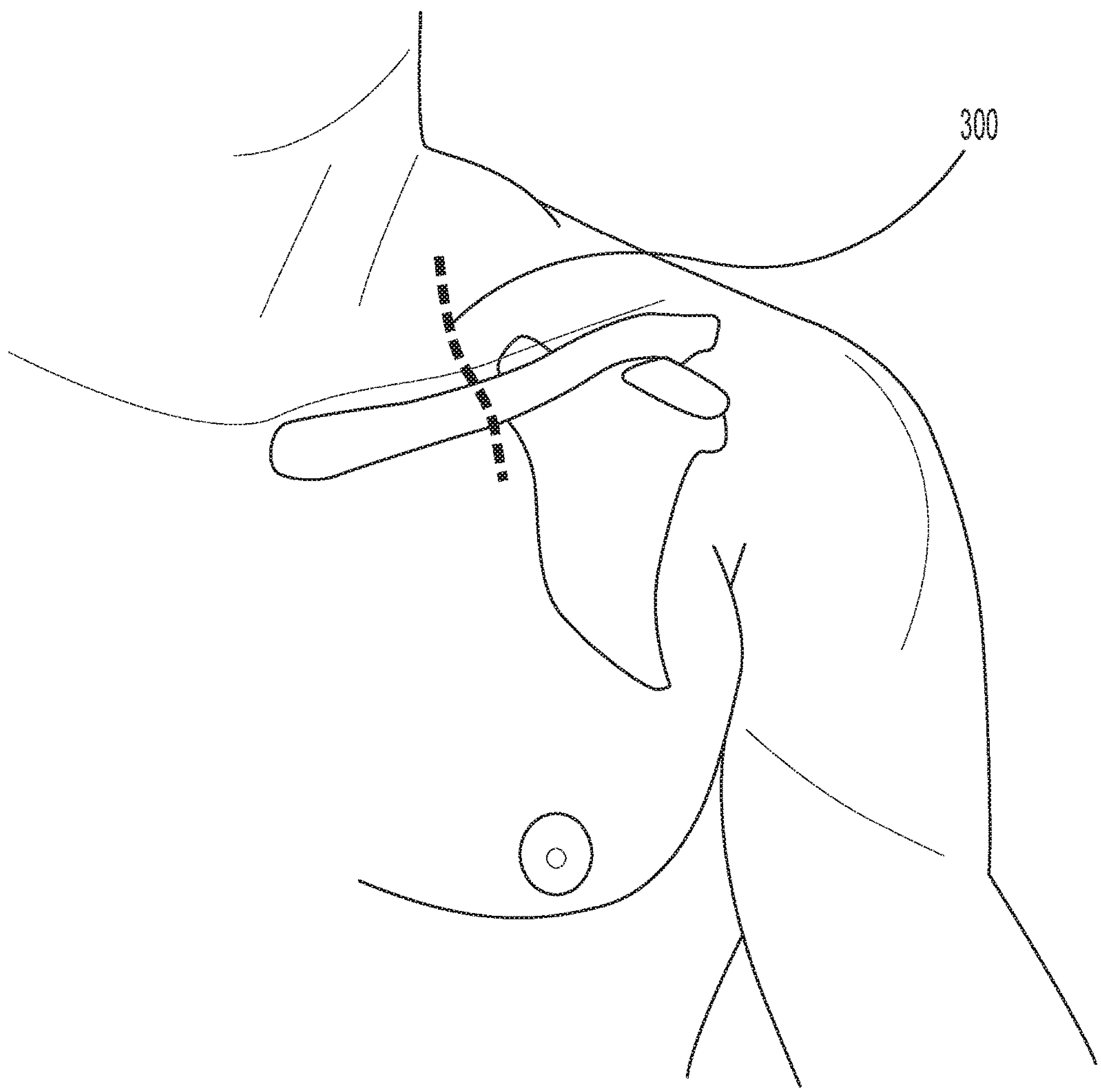

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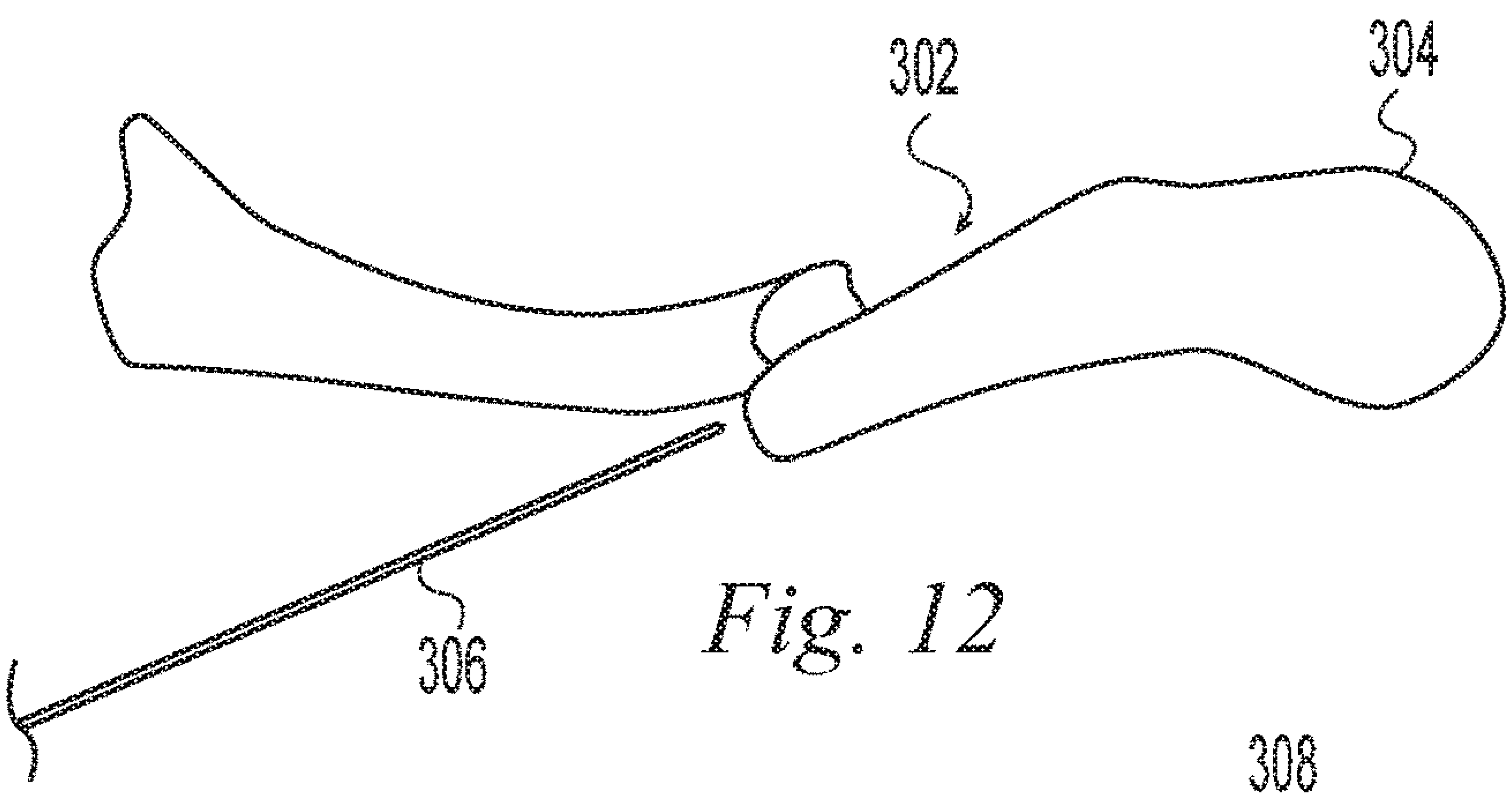

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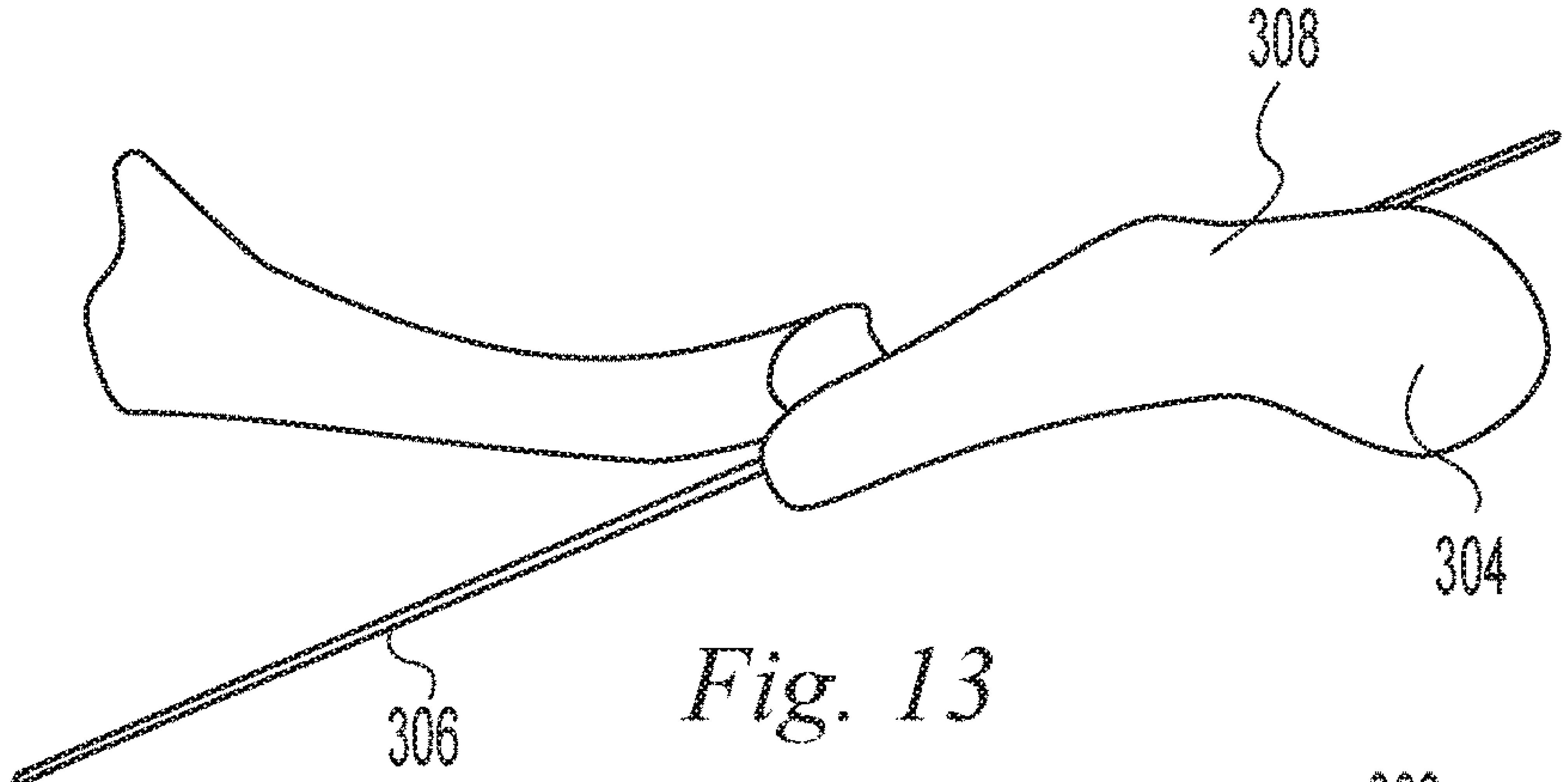

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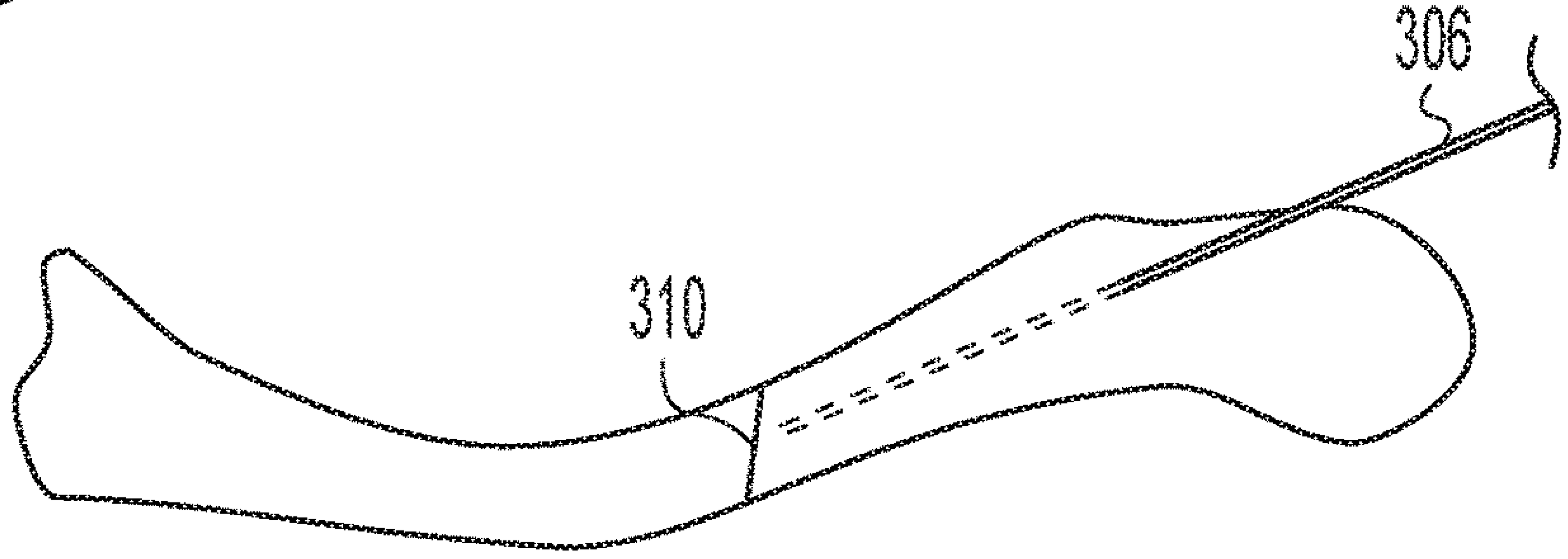

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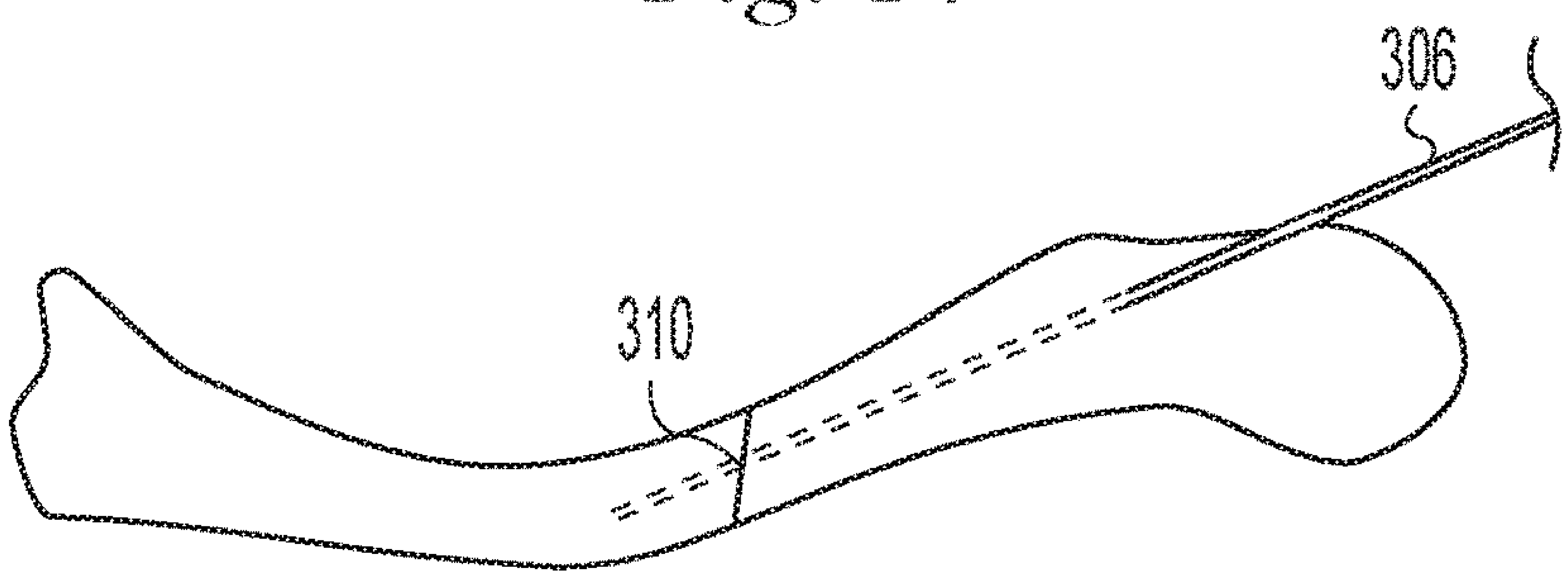

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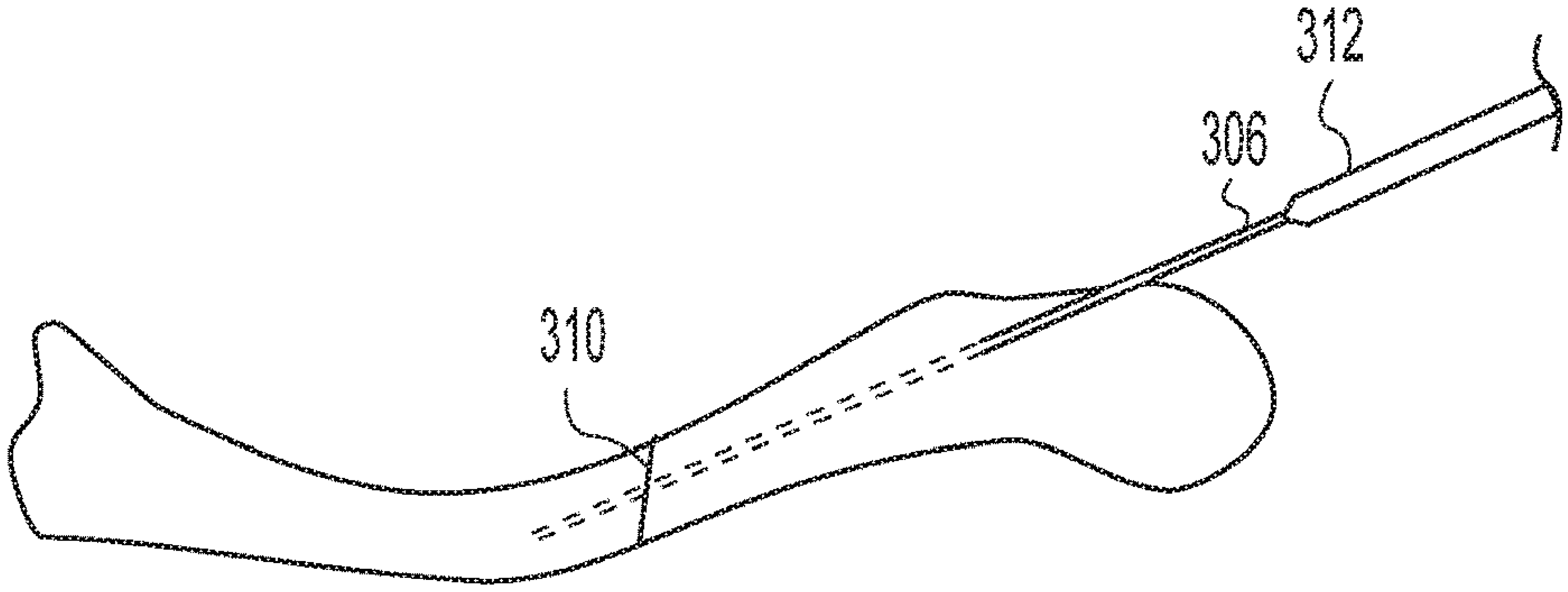

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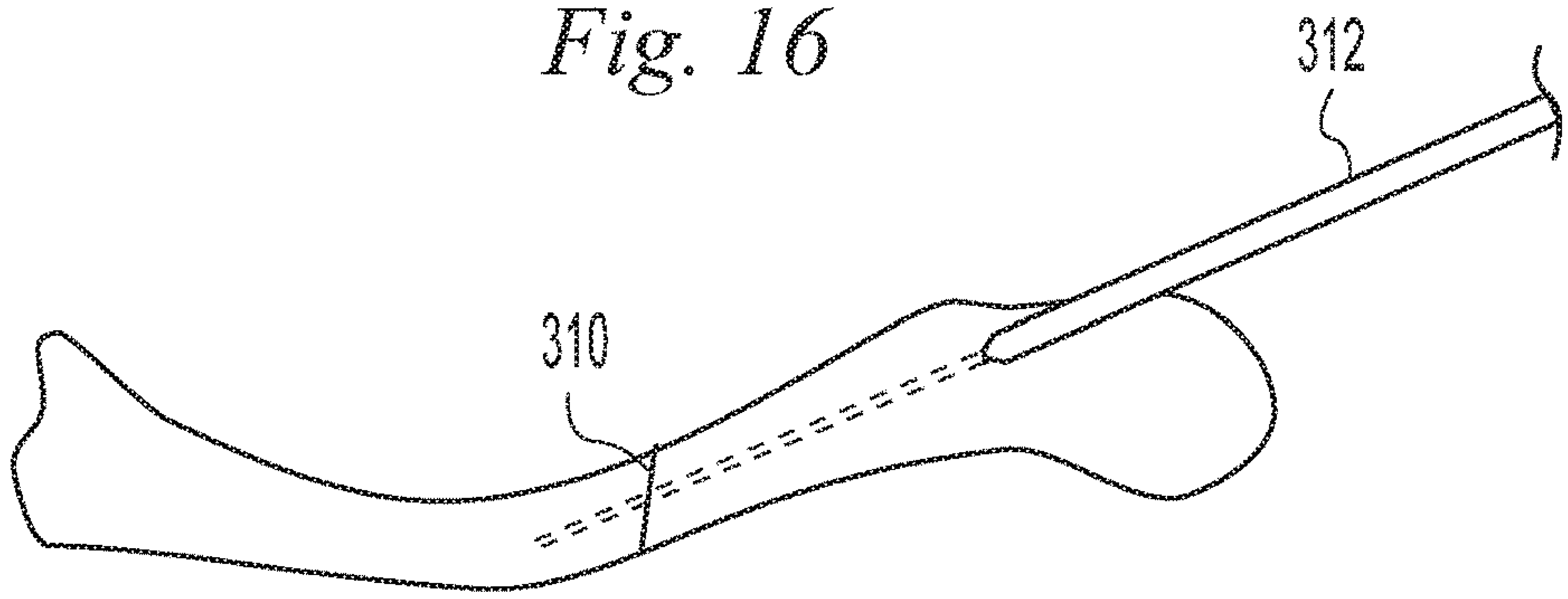

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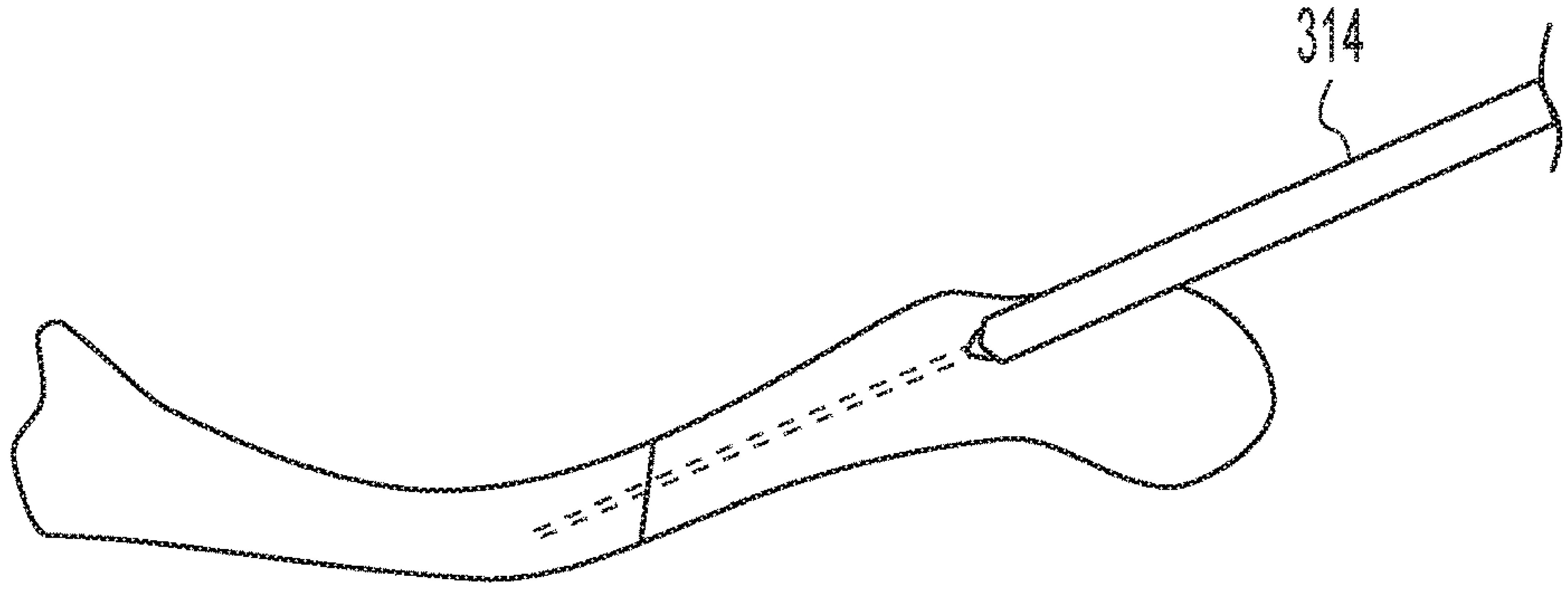

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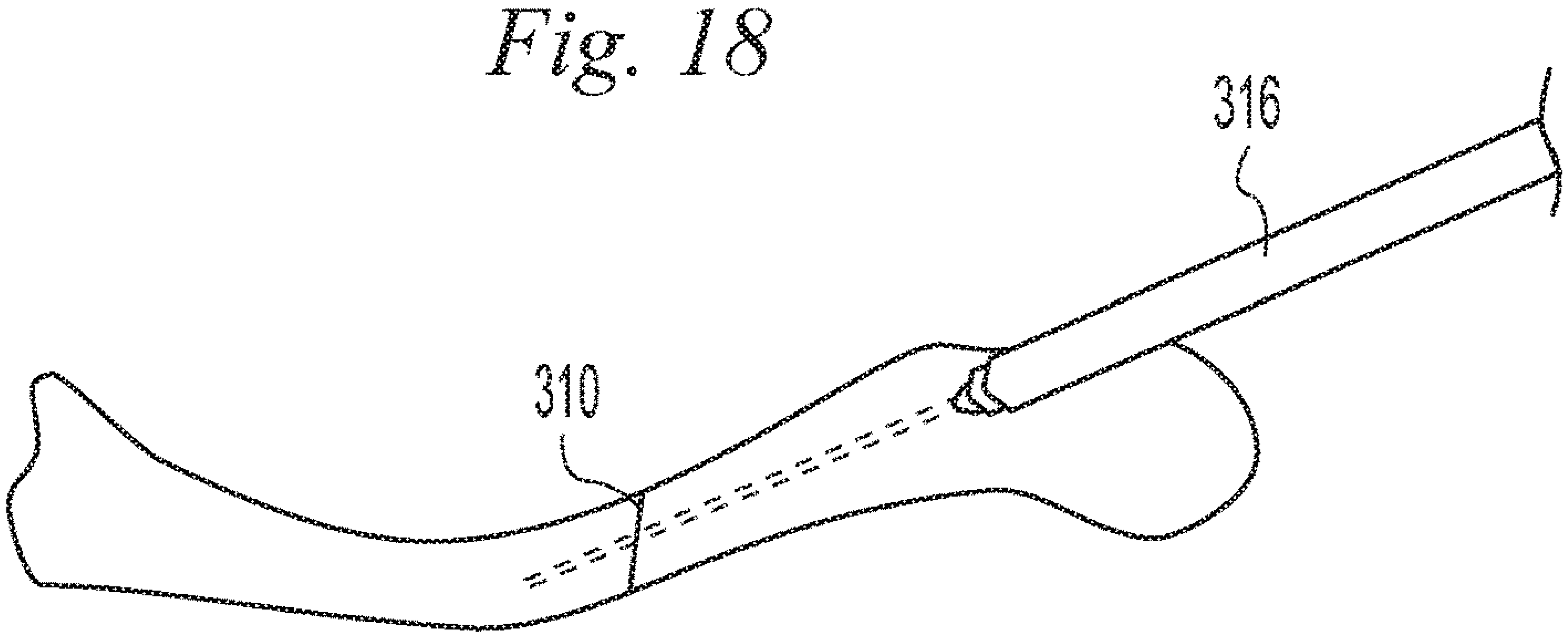

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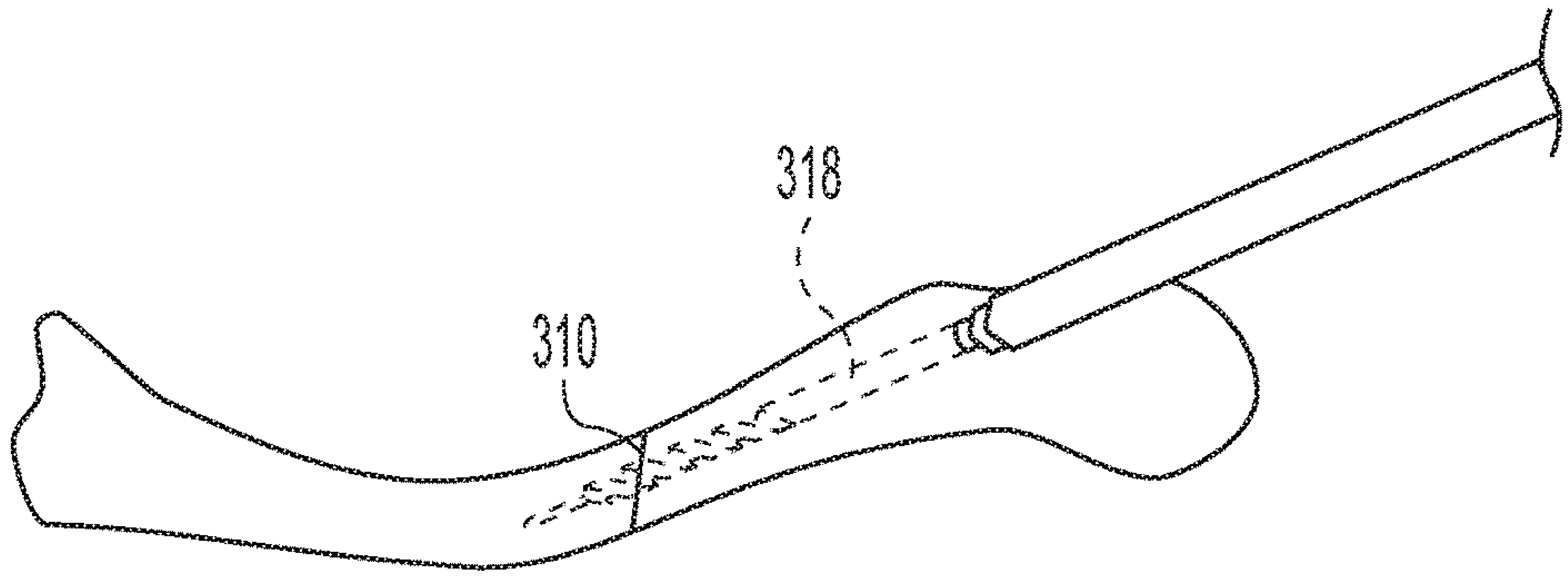

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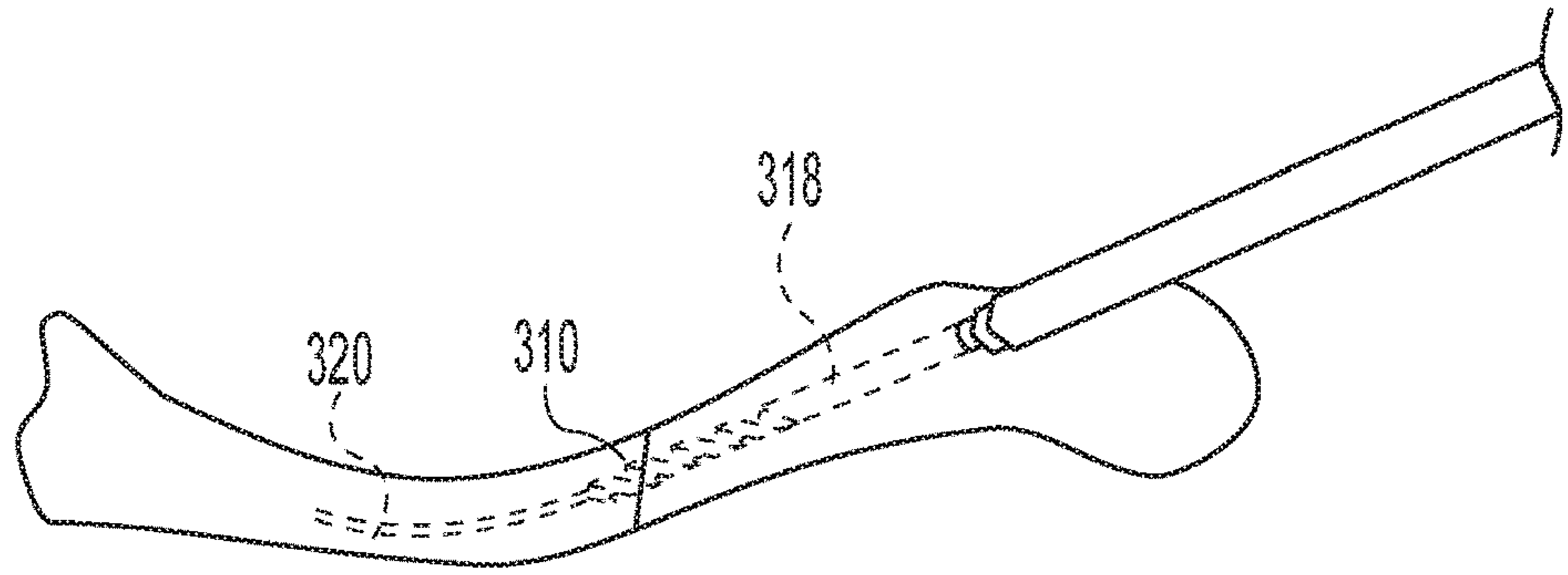

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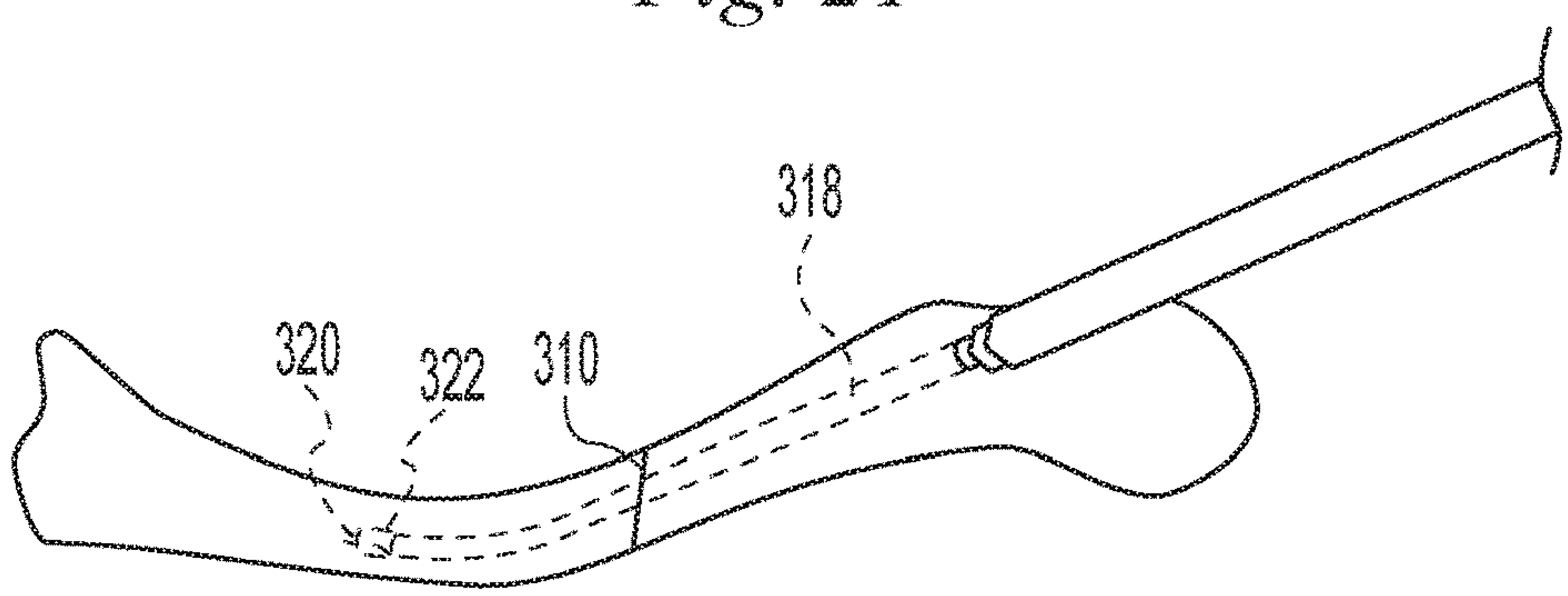

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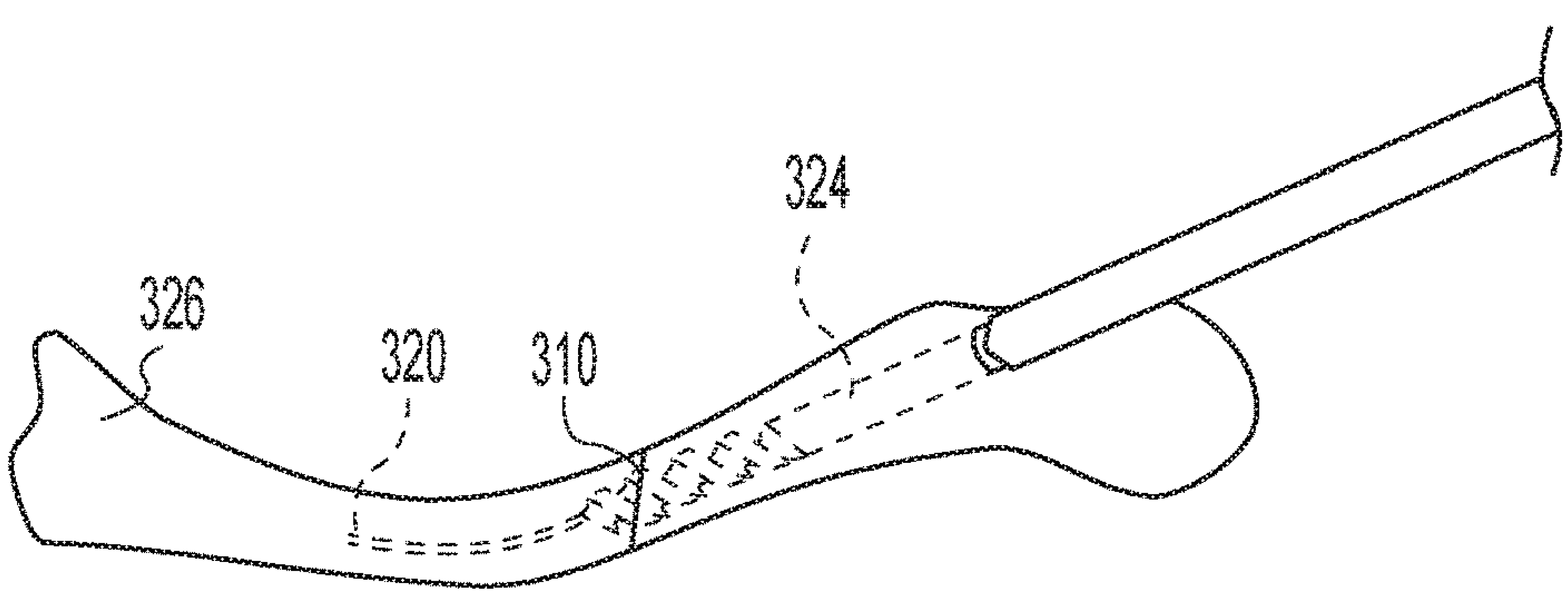

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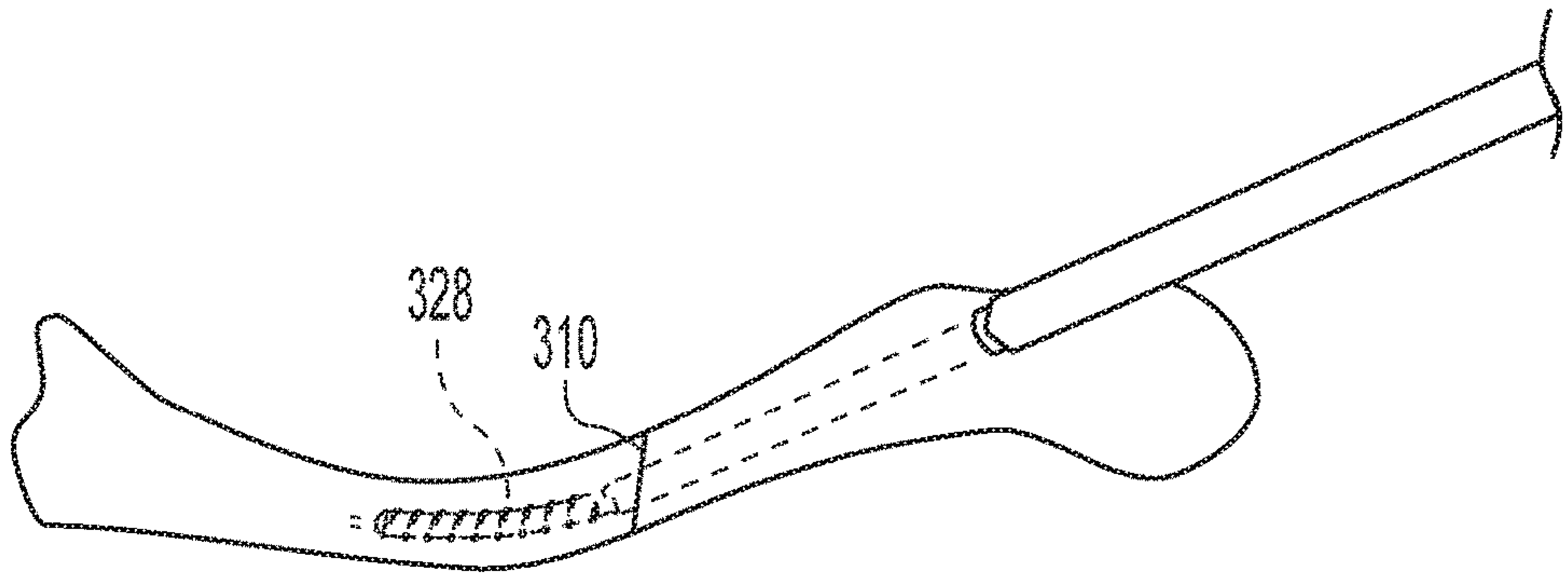

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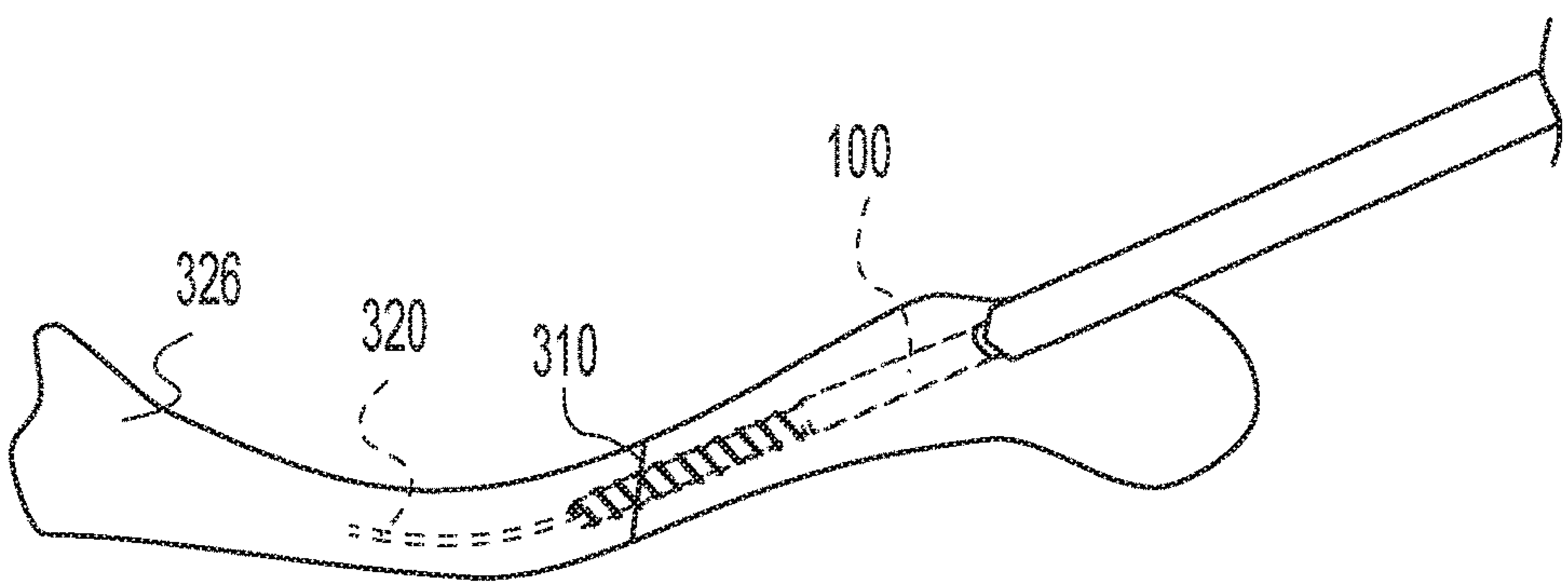

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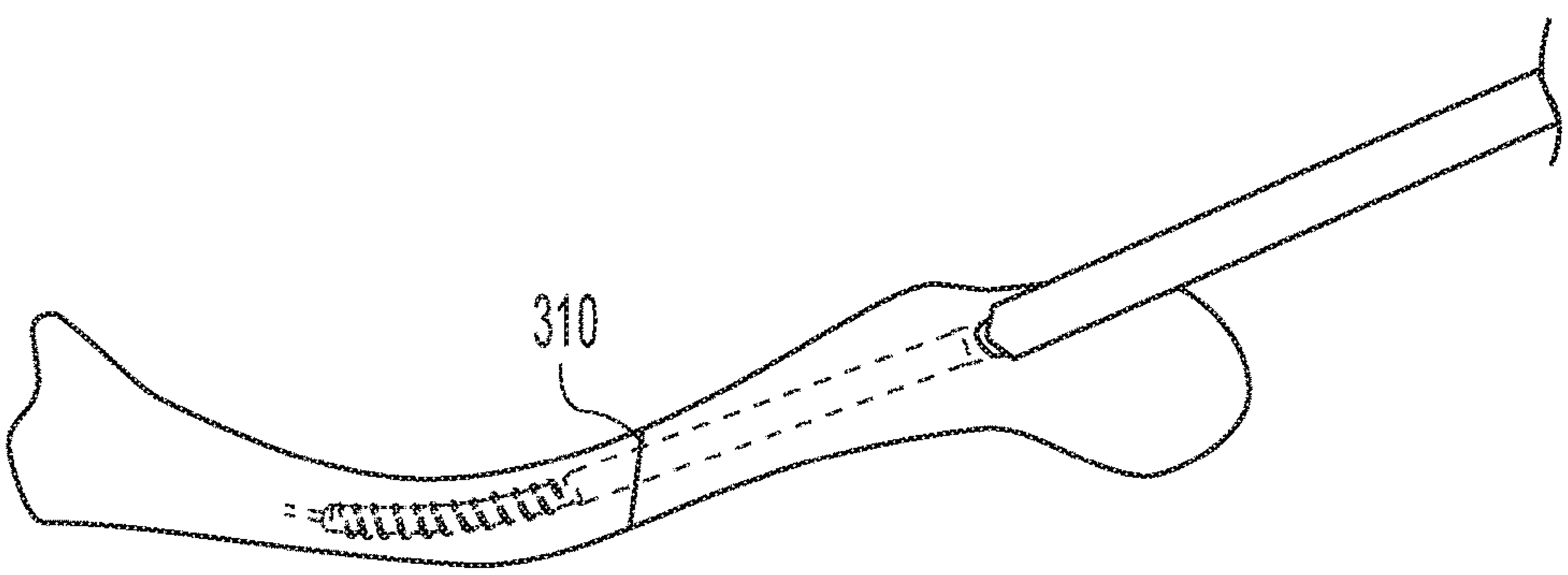

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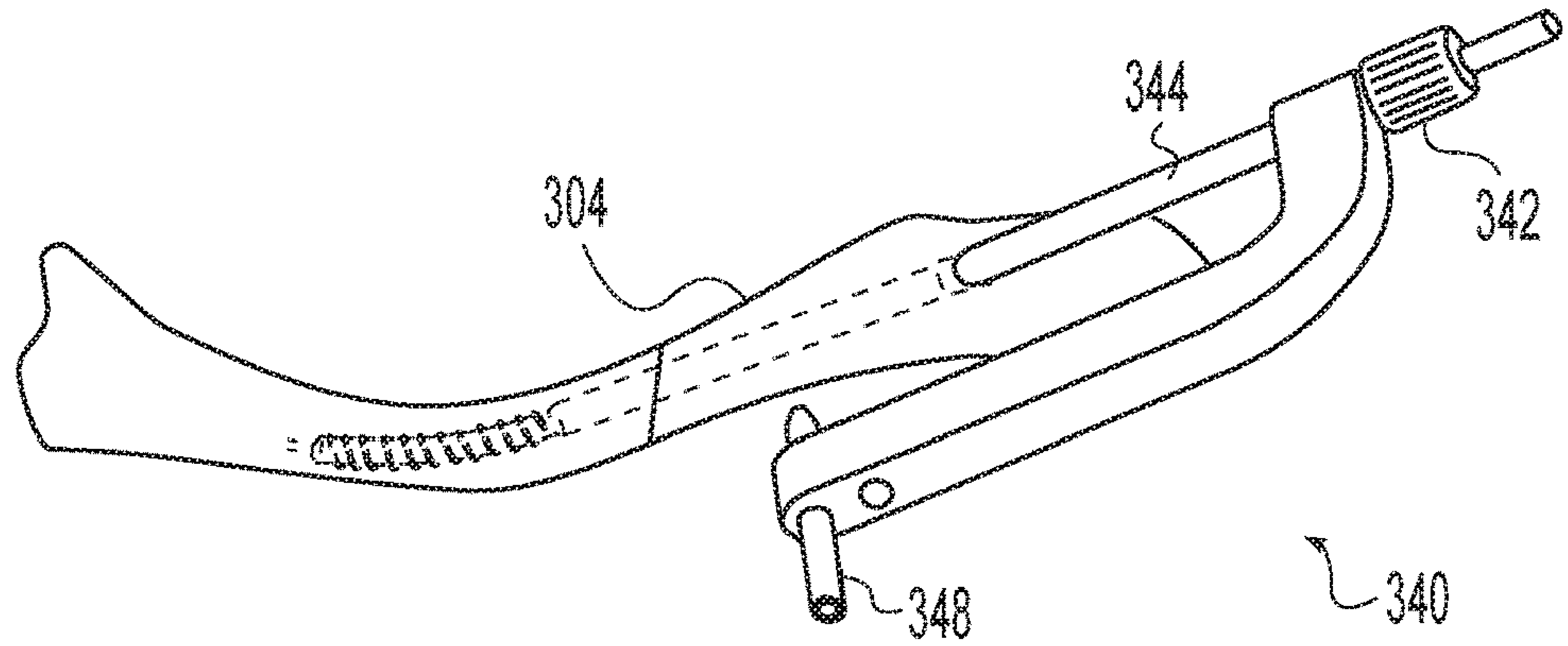

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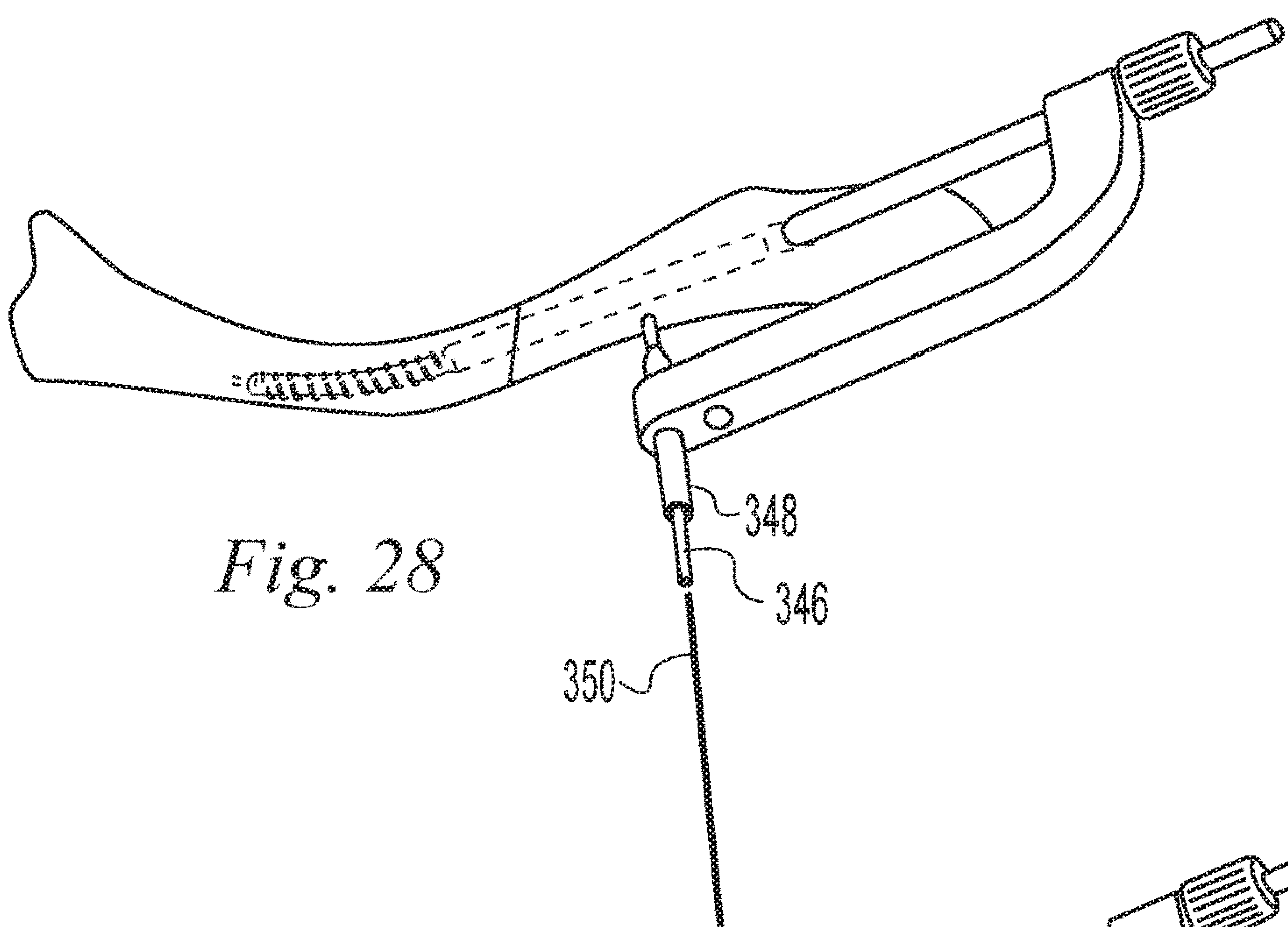

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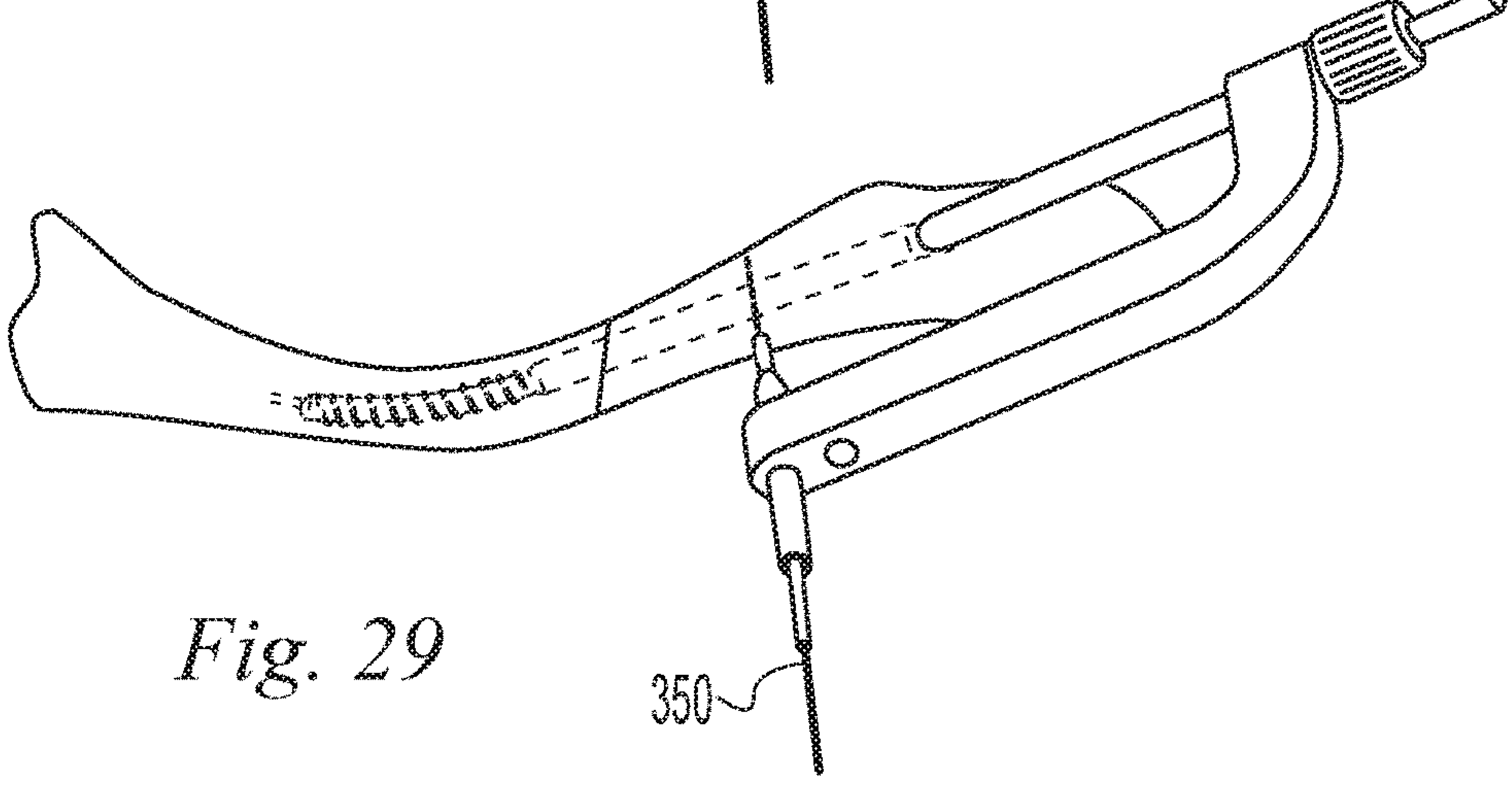

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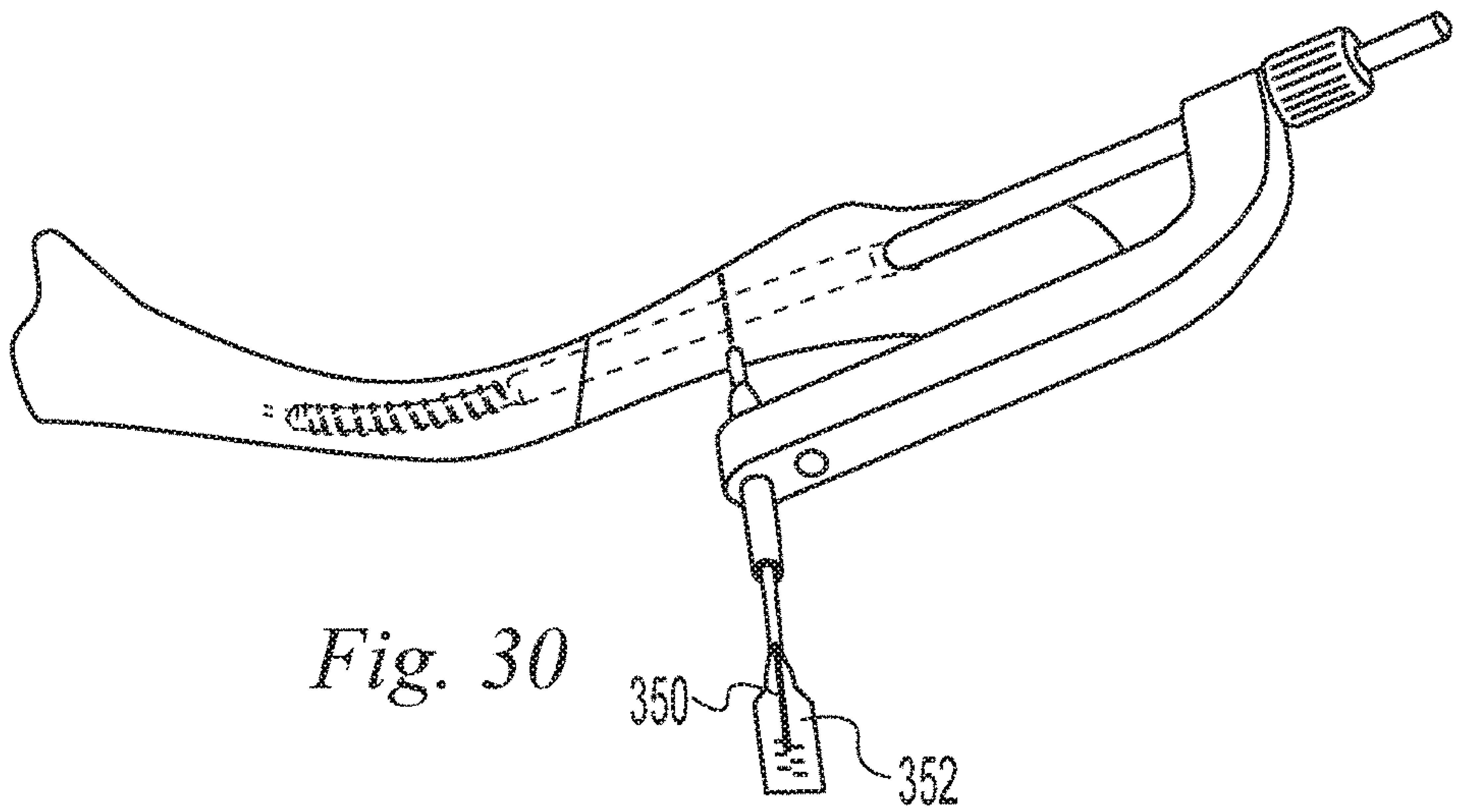

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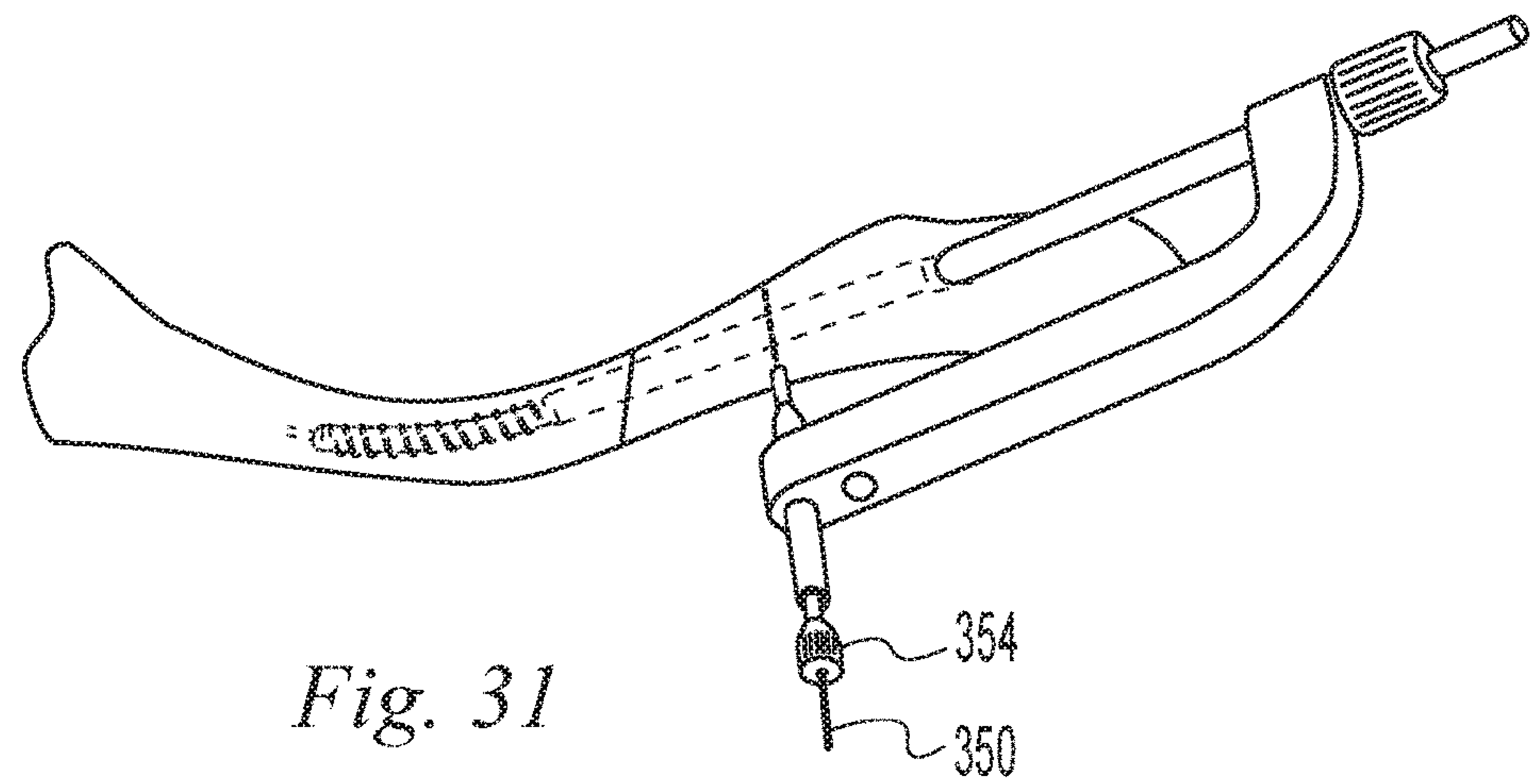
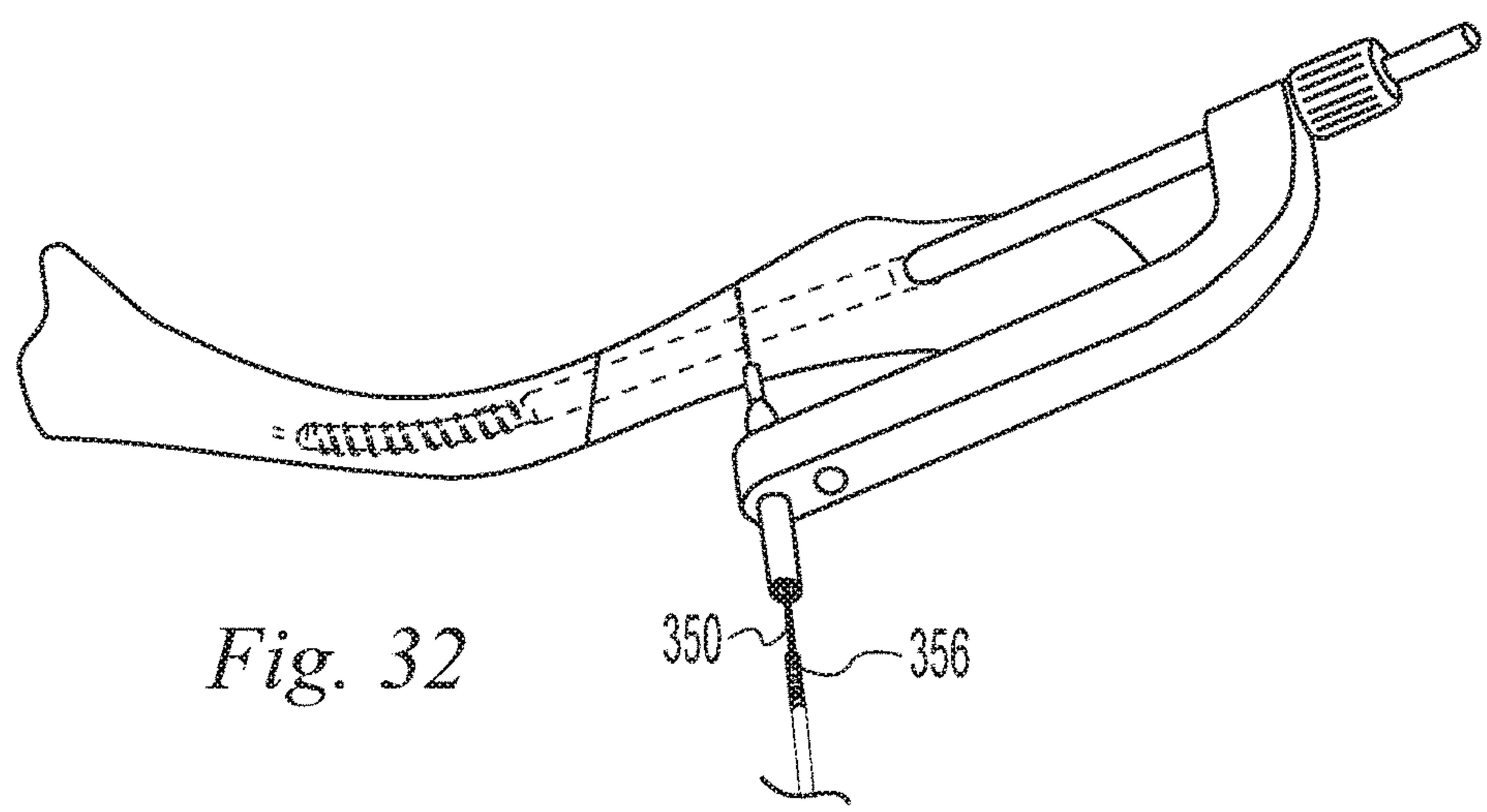


Fig. 31



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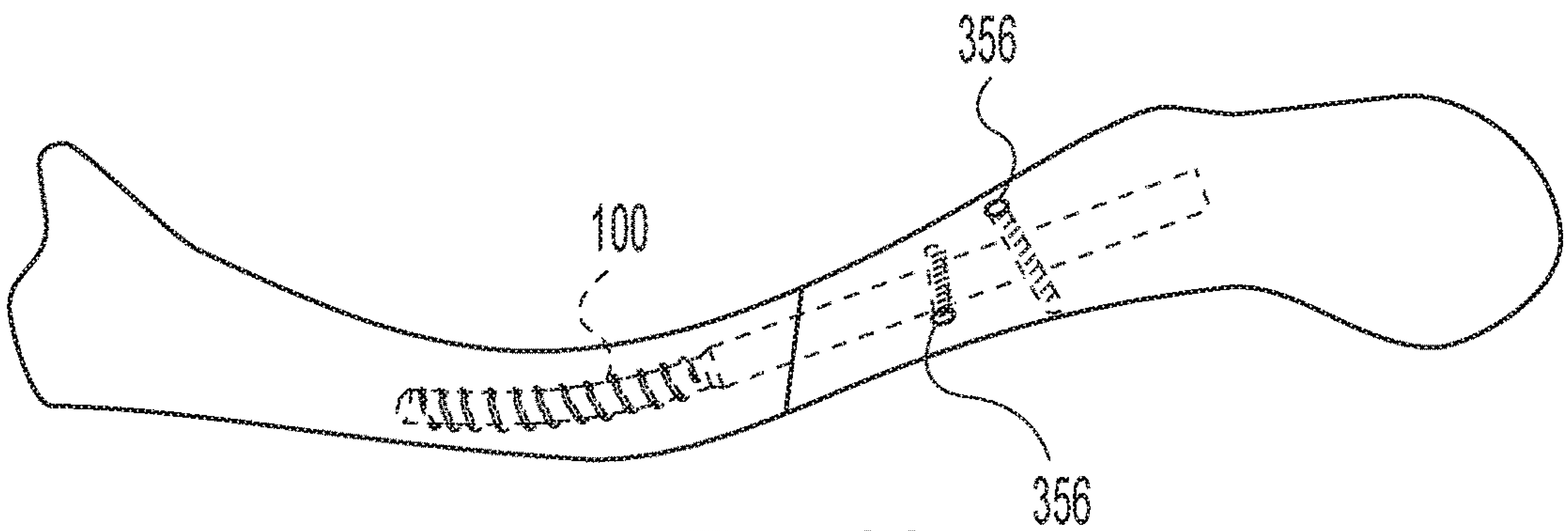

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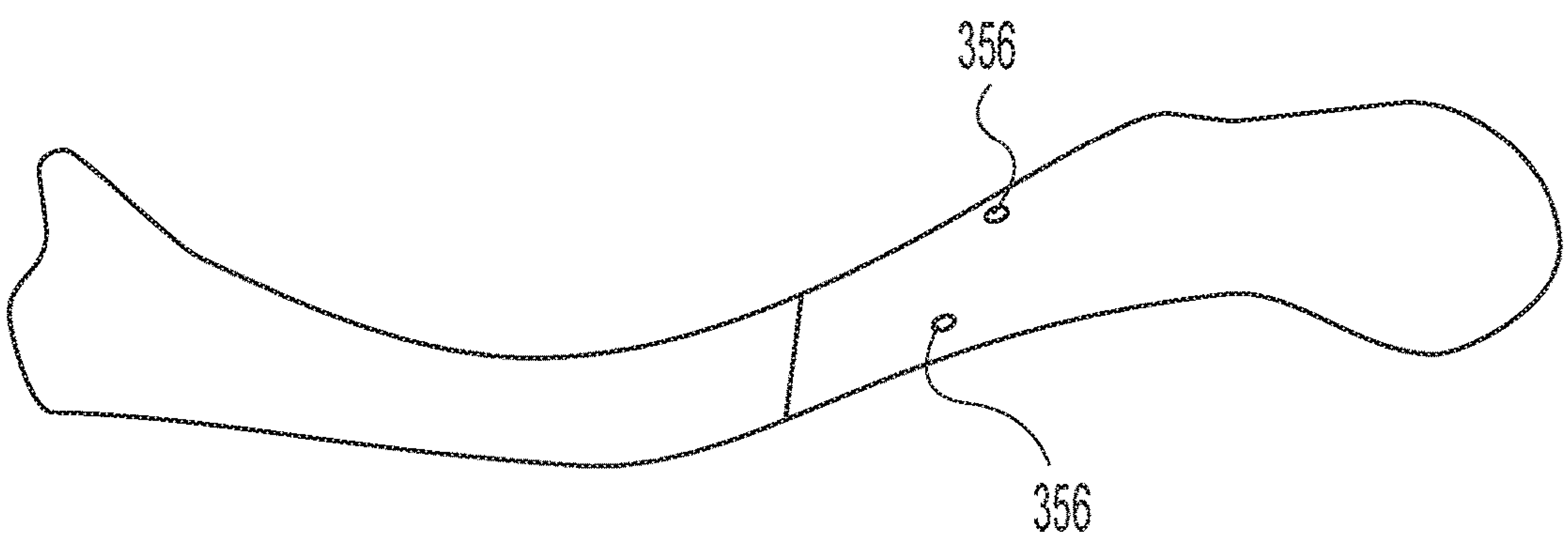

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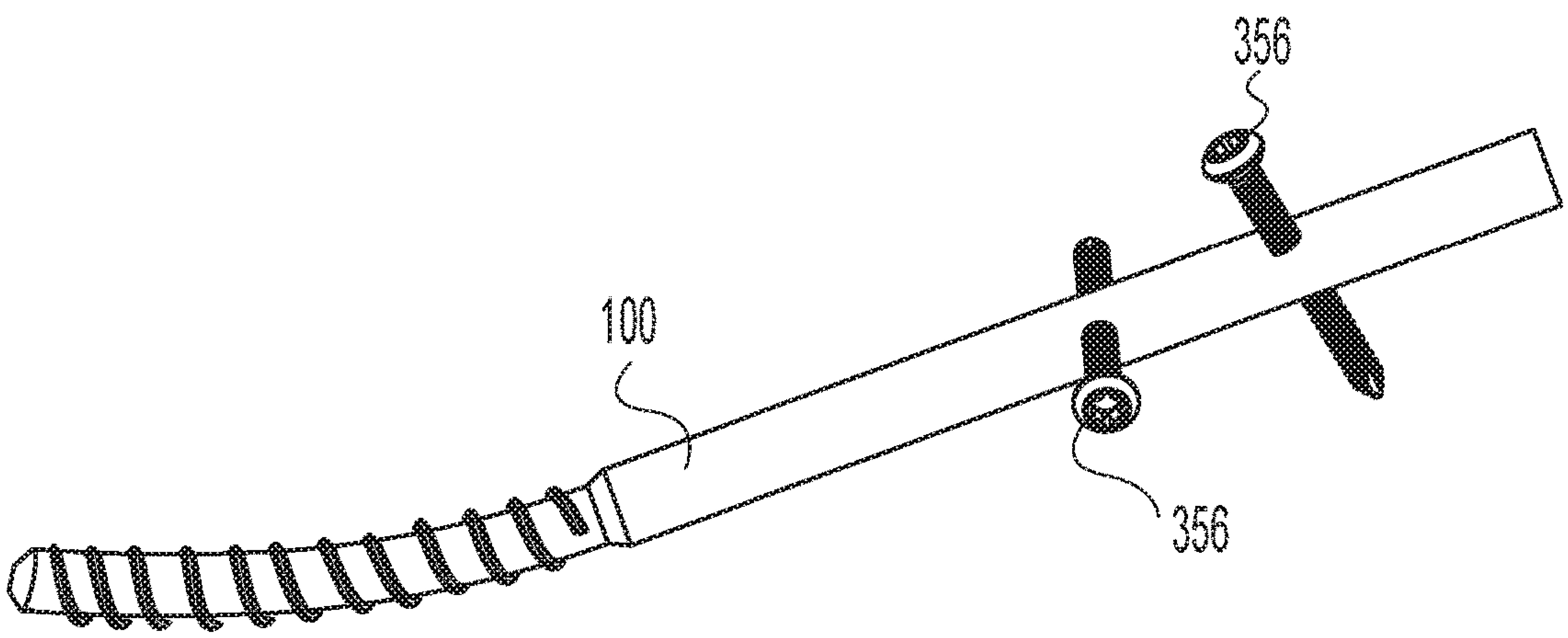

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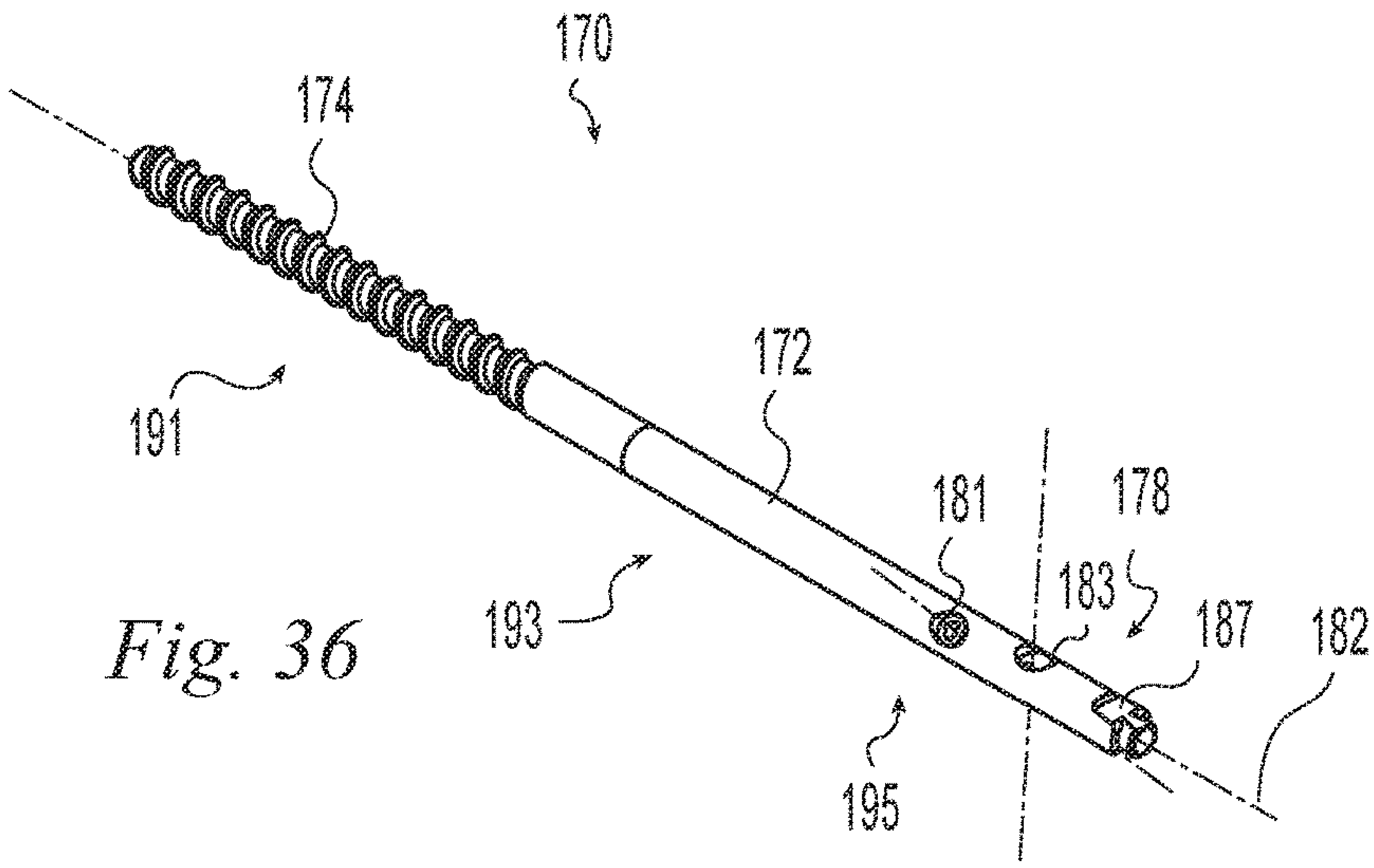


Fig. 36

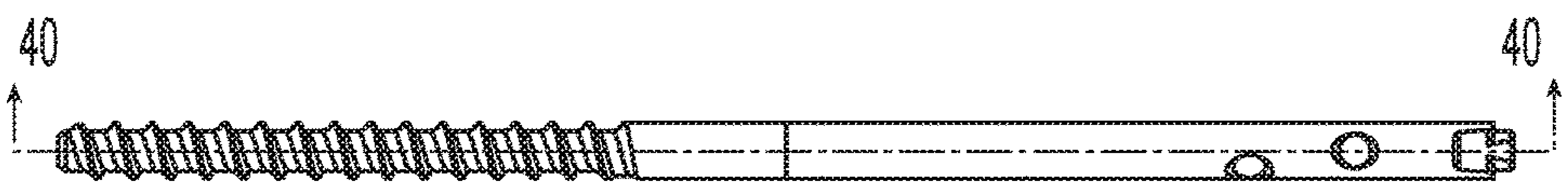
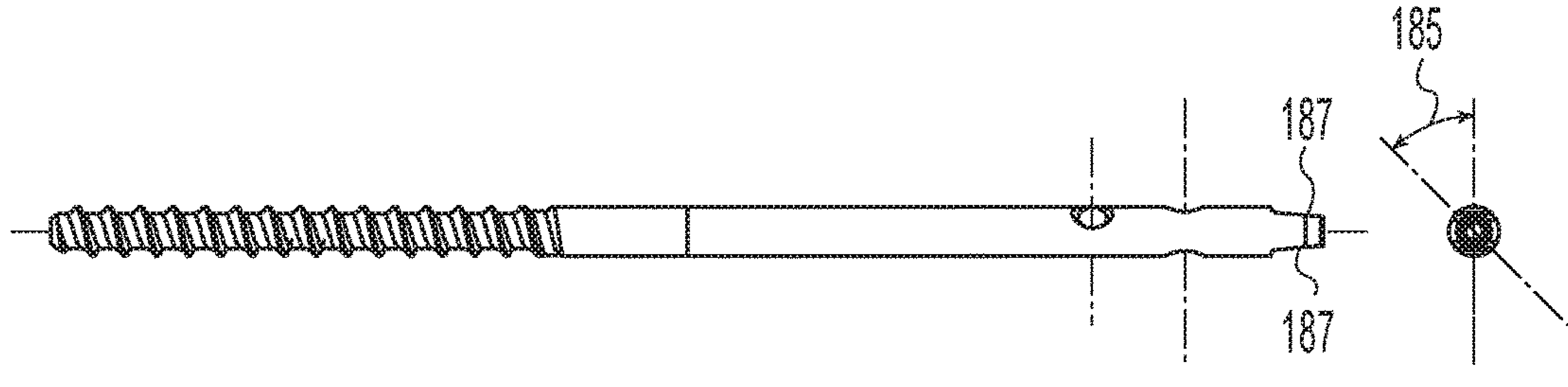


Fig. 37



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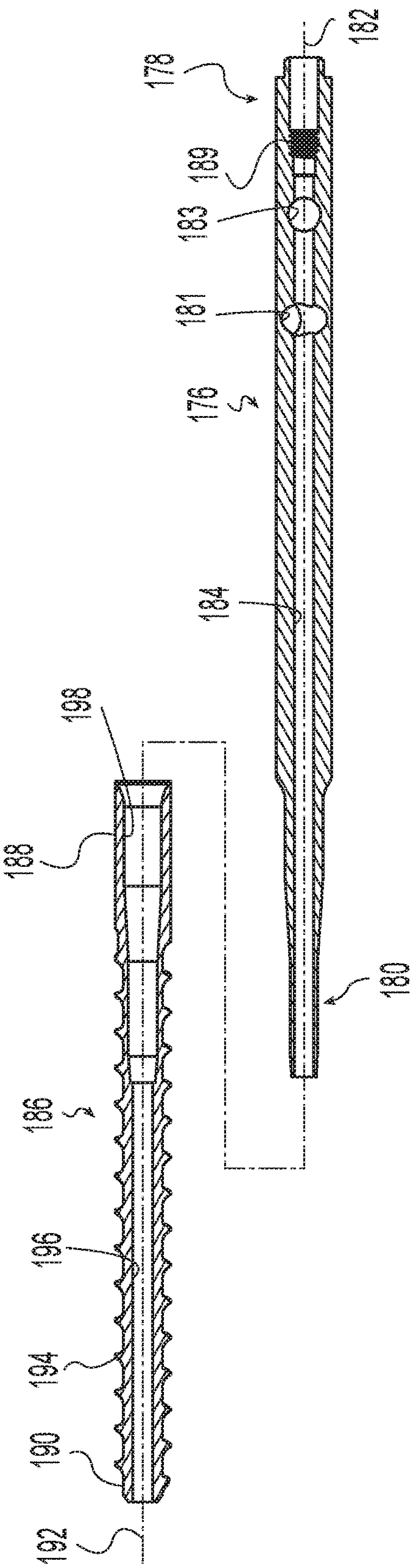
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Fig. 41

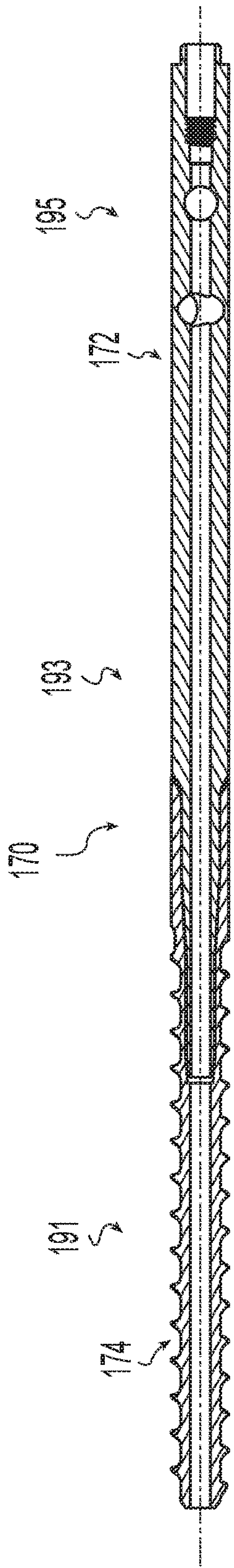
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Fig. 40

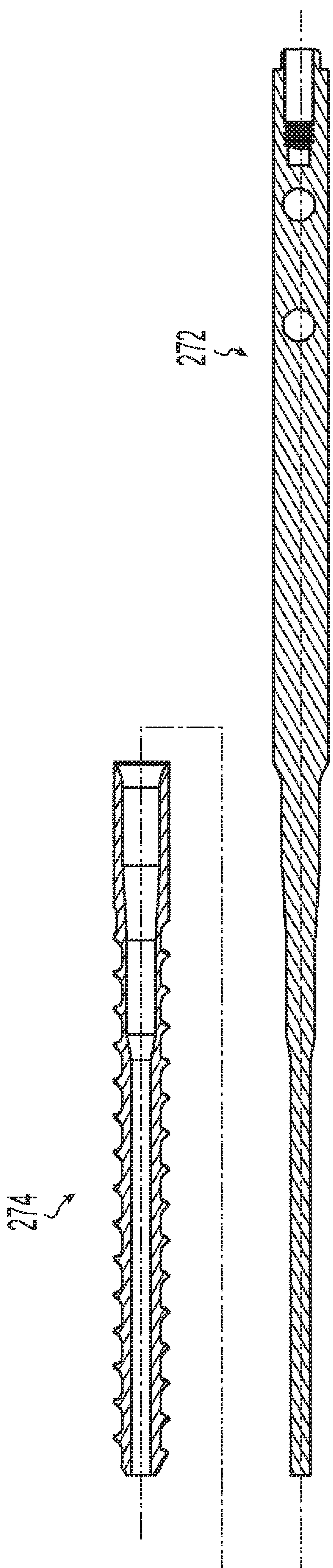

Fig. 43

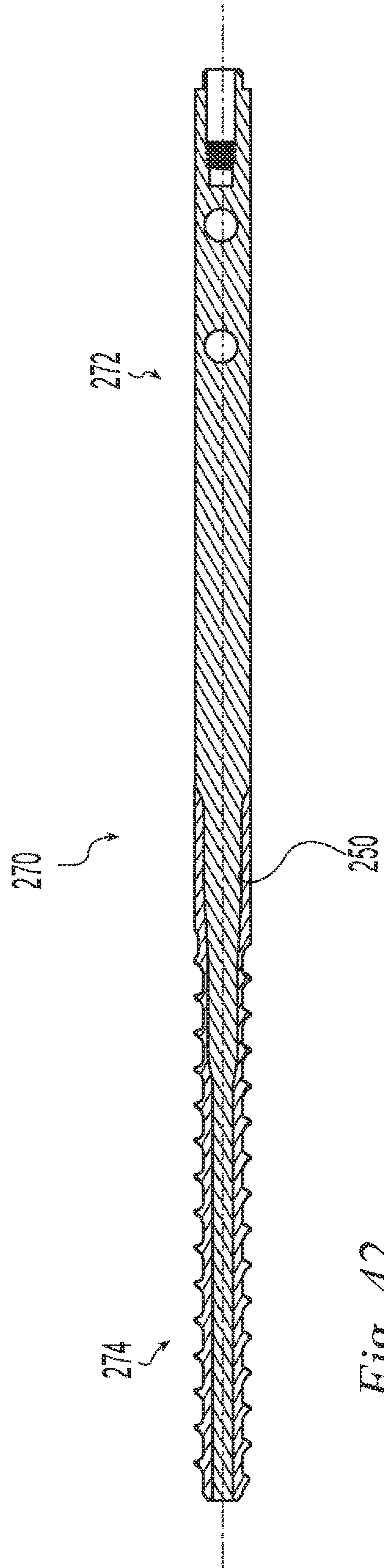

Fig. 42

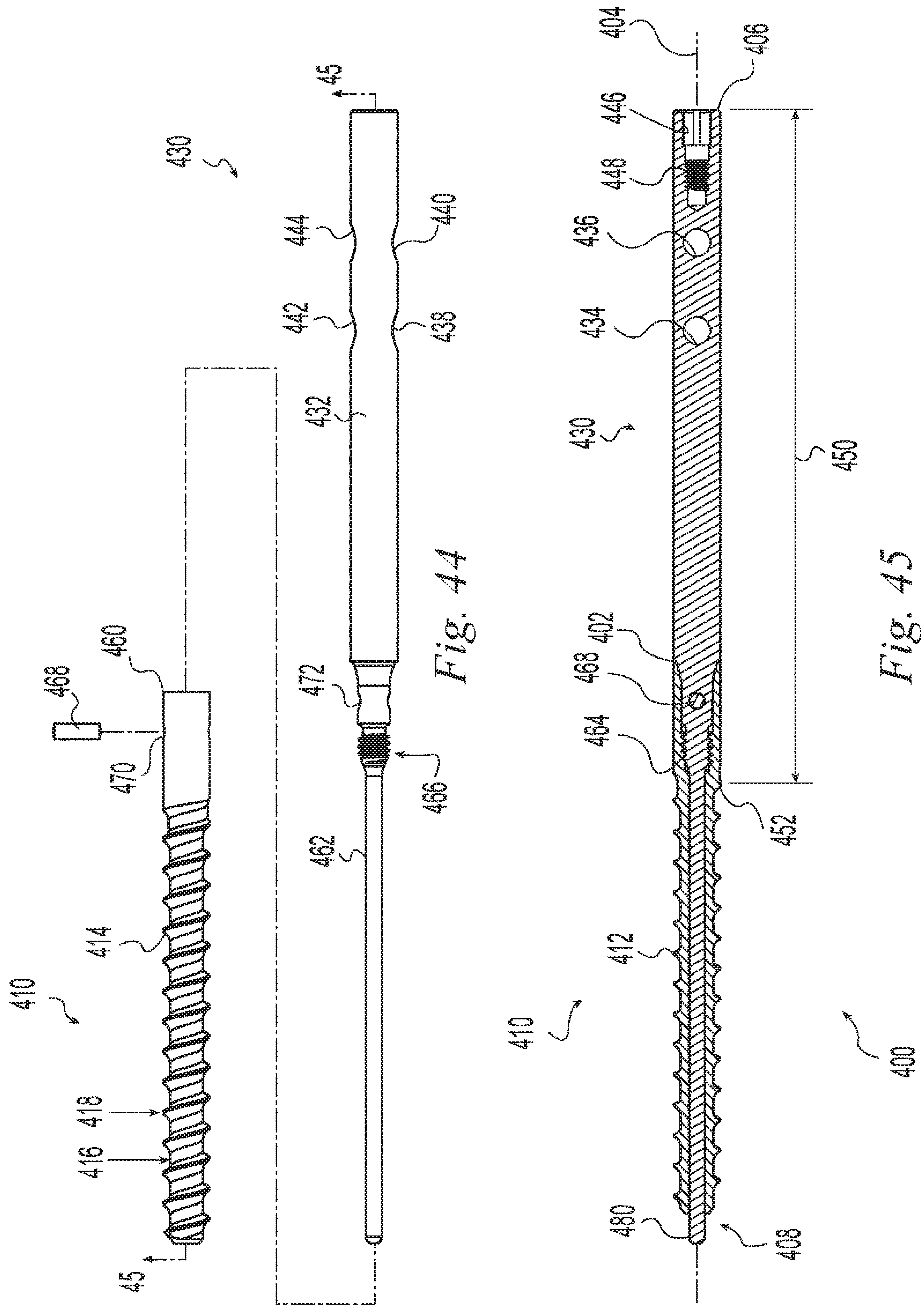
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Fig. 44

Fig. 45

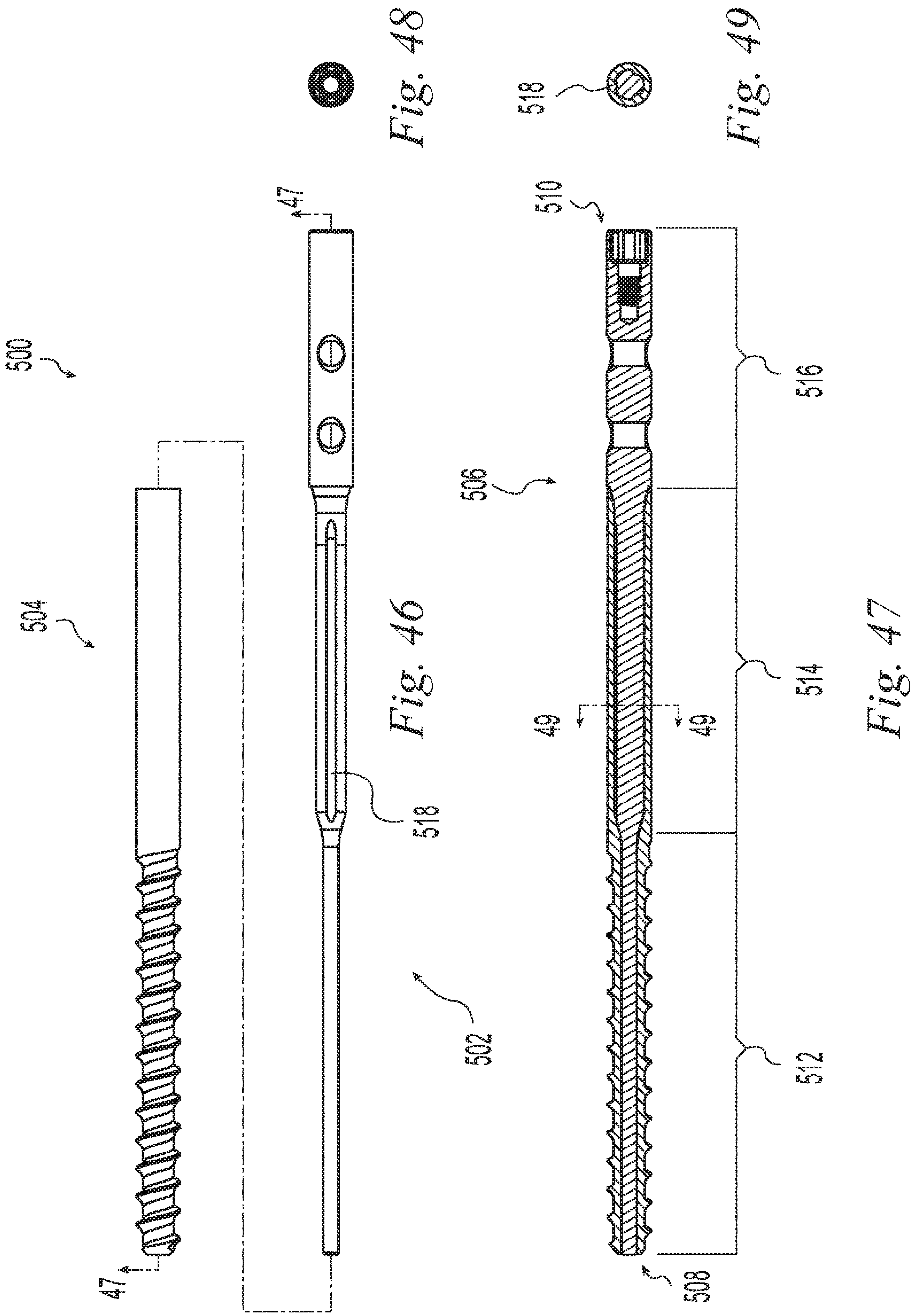

Fig. 46

Fig. 47

Fig. 48

Fig. 49

FLEXIBLE BONE SCREW

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 15/197,879, filed Jun. 30, 2016, which claims the benefit of U.S. Provisional Application No. 62/191,904, filed Jul. 13, 2015, and U.S. Provisional Application No. 62/238,780, filed Oct. 8, 2015, all of which are hereby incorporated by reference.

FIELD OF THE INVENTION

Examples of the invention relate generally to orthopedic devices for the surgical treatment of bone and, more particularly, to the stabilization of bones with an intramedullary device.

BACKGROUND

Orthopedic medicine provides a wide array of implants that can be attached to bone to repair fractures. External fixation involves the attachment of a device that protrudes out of the skin, and therefore carries significant risk of infection. Many fractures in long bones can be repaired through the use of bone plates, which are implanted and attached to lie directly on the bone surface. The bone plate then remains in the body long enough to allow the fractured bone to heal properly. Unfortunately, such bone plates often require the surgical exposure of substantially the entire length of bone to which the plate is to be attached. Such exposure typically results in a lengthy and painful healing process, which must often be repeated when the implantation site is again exposed to allow removal of the plate. There is a need in the art for implants and related instruments that do not require such broad exposure of the fractured bone, while minimizing the probability of infection by avoiding elements that must protrude through the skin as the bone heals.

SUMMARY

Examples of the invention provide devices and methods for stabilizing first and second bone portions relative to one another.

In one example of the invention, a device for stabilizing a fracture in a bone includes a body having an elongate distal portion having an outer surface defining a screw thread and an elongate proximal portion having a non-threaded outer surface.

In another example of the invention, a passage is formed through the proximal portion transverse to the longitudinal axis from a first opening on the surface of the proximal portion to a second opening on the surface of the proximal portion.

In another example of the invention, a method of stabilizing a fractured long bone having an intramedullary canal, comprises providing a bone implant comprising a body defining a longitudinal axis extending between a proximal end and a distal end; an elongate distal portion of the body having an outer surface defining a screw thread, the screw thread having a minor diameter and a major diameter; and an elongate proximal portion of the body having a non-threaded outer surface, a passage formed through the proximal portion transverse to the longitudinal axis from a first opening on the surface of the proximal portion to a second opening on the surface of the proximal portion; and inserting the bone implant into an intramedullary canal of a bone so that the proximal portion spans a fracture in the bone.

BRIEF DESCRIPTION OF THE DRAWINGS

Various examples of the invention will be discussed with reference to the appended drawings. These drawings depict only illustrative examples of the invention and are not to be considered limiting of its scope.

FIG. **1** is a side elevation view of a screw according to one example of the invention;

FIG. **2** is a detail view of the screw of FIG. **1**;

FIG. **3** is a detail view of the screw of FIG. **1**;

FIG. **4** is an end view of the screw of FIG. **1**;

FIGS. **5-7** are side elevation views of a set of differently sized screws like that of FIG. **1**;

FIGS. **8-10** are partial sectional views showing the insertion of the screw of FIG. **1** into bone;

FIGS. **11-35** illustrate a surgical procedure utilizing the bone screw of FIG. **1**;

FIG. **36** is a perspective view of a screw according to one example of the invention;

FIG. **37** is a top plan view of the screw of FIG. **36**;

FIG. **38** is a side elevation view of the screw of FIG. **36**;

FIG. **39** is an end view of the screw of FIG. **36**;

FIG. **40** is a sectional view taken along line **40-40** of FIG. **37**;

FIG. **41** is an exploded sectional view taken along line **40-40** of FIG. **37**;

FIG. **42** is a cross sectional view of a screw according to one example of the invention;

FIG. **43** is an exploded cross sectional view of the screw of FIG. **42**;

FIG. **44** is an exploded side view of a screw according to one example of the invention;

FIG. **45** is an assembled sectional view taken along line **45-45** of FIG. **44**;

FIG. **46** is an exploded side view of a screw according to one example of the invention;

FIG. **47** is an assembled sectional view taken along line **47-47** of FIG. **46**;

FIG. **48** is an end view of the screw of FIG. **46**; and

FIG. **49** is a cross sectional view taken along line **49-49** of FIG. **47**.

DESCRIPTION OF THE ILLUSTRATIVE EXAMPLES

The term "transverse" is used herein to mean not parallel.

FIGS. **1-4** depict a bone screw **100** according to one example of the invention having an elongate body **102** with a distal portion **104**, a mid-portion **106** and a proximal portion **108** spaced longitudinally relative to a longitudinal axis **110**. The distal portion **104** includes a helical thread **112** having a major diameter **114**, a minor diameter **116**, and a pitch **128**. The mid-portion **106** has a non-threaded outer surface **118** with an outer diameter **120**. In the illustrative example of FIGS. **1-4**, the mid-portion outer diameter **120** is equal to or greater than the thread major diameter **114**. The distal threaded portion **104** is operable to bend as it is threaded into a bone to follow a curved path. For example, the bending stiffness of the distal threaded portion **104** is such that it will bend to follow a curved path in human bone. Such a curved path may be defined, for example, by a curved hole in the bone, a guide wire, or a natural bone feature such as a non-linear intramedullary canal bounded by cortical bone.

This is distinct from prior art screws which if started on a curved path in human bone would, when advanced, continue in a straight line and thus deviate from the curved path and form their own, straight, path through the bone. Preferably the bending stiffness of the threaded distal portion **104** is lower than the bending stiffness of the mid-portion **106**. The relatively lower bending stiffness of the threaded distal portion **104** causes the threaded distal portion to bend to follow a curved path while the relatively higher bending stiffness of the mid-portion causes the mid-portion to remain straight to stabilize first and second bone portions relative to one another at a bone interface such as at a fracture, osteotomy, or fusion site. The difference in bending stiffness between the threaded distal portion **104** and the mid-portion **106** may be achieved in different ways. For example, the threaded distal portion **104** and the mid-portion **106** may be made of different materials and/or may have different sectional moduli. In the illustrative example of FIGS. **1-4**, the threaded distal portion **104** and the mid-portion **106** have different sectional moduli. The threaded distal portion minor diameter **116** is less than the outer diameter **120** of the mid-portion **106** and the threaded distal portion major diameter is less than or equal to the outer diameter **120** of the mid-portion **106**. Preferably, the ratio of the bending stiffness of the mid-portion **106** to the bending stiffness of the threaded distal portion **104** is in the range of 1.5:1 to 100:1. More preferably, the ratio is in the range of 2:1 to 20:1. For example, screws suitable for internal fixation of a clavicle fracture and that fall within these ranges may have a major diameter **114** in the range of 4-6.5 mm, a minor diameter **116** in the range of 2.5-3.5 and a cannulation **101** with a diameter in the range of 1-2 mm. Preferably, the screw **100** is made of a polymer.

Table 1 compares the calculated load required to bend a cantilevered tube of 3 mm outside diameter and 1.5 mm inside diameter around a radius of 50 mm and an arc length of 26 mm. The titanium and stainless steel alloys are predicted to have a required load approximately 10 times that of the PEEK and PLLA. These loads would be greater than the bone could withstand and a threaded device made of those materials would not follow a curved path in the bone but would instead cause the bone to fail. In the case of the highly cold worked stainless steel, even if the bone could withstand the load, the screw would fail since the minimum bend radius before failure of the screw is greater than 50 mm.

TABLE 1

Load at 50 mm bend radius

Material	Yield Stress (MPa)	Failure Stress (MPa)	Yield Strain (%)	Failure Strain (%)	Flexural Modulus (MPa)	Load (N)
PEEK ASTM F2026	100	115	2.5%	20%	4	9.8
PLLA	90	100	2.6%	25%	3.5	8.7
Ti—6Al—4V ELI ASTM F136	880	990	0.8%	14%	114	91.7
316LVM Stainless Steel ASTM F899	1468	1696	0.7%	3%	197	Not possible

Another way to quantify the bending stiffness of the threaded distal portion **104** is by the amount of torque required to turn the threaded distal portion **104** into a curved bone hole having a specified radius of curvature. For example, the threaded distal portion **104** preferably requires a torque less than 20 in-lbs to turn the distal threaded portion **104** into a bone to follow a curved path having a radius of curvature of 50 mm. More preferably the required torque is less than 10 in-lbs. More preferably the required torque is less than 5 in-lbs. More preferably the required torque is approximately 2 in-lbs.

Table 2 compares the measured torque required to advance a threaded tube 25 mm into a 50 mm threaded radius formed in a rigid test block. The tubes were all machined to the same geometry but of different materials. The thread major diameter was 4.25 mm, the minor diameter was 3.0 mm and the inner diameter of the tube was 1.5 mm. A rigid block was prepared having a curved, threaded path. Such a path has a pitch that is wider on the outside of the curve and a pitch that is narrower on the inside of the curve corresponding to the shape of the screw thread when it is curved. Multiple samples of each screw were inserted into the block over an arc length of 25 mm. The maximum torque for each revolution was measured and it was found that the torque increased for each revolution. In Table 2, the range is the range of torque values from the first to the last revolution. The average is the average of the torque values for all revolutions. The peak is the highest torque value and in all cases occurred in the last revolution. However, the torque values for each material were relatively constant over the last few revolutions. The titanium and stainless steel alloys had measured torque values approximately 10 times that of the PEEK. These tests were conducted using a threaded block made of tool steel with a strength greater than that of the materials being tested in order to compare the torque values. As pointed out relative to Table 1, the loads generated from the metal implants would be greater than the bone could withstand and a threaded device as described herein made of these metals would not follow a curved path in the bone but would instead cause the bone to fail.

TABLE 2

Torque to thread around rigid 50 mm radius

Material	Range (in-lbs)	Average (in-lbs)	Peak (in-lbs)
PEEK ASTM F2026	0-2.0	1.4	2.0
Ti—6Al—4V ELI ASTM F136	0.7-25	16	25
316LVM Stainless Steel ASTM F899	0.5-20	13	20

In addition to bending stiffness advantages, having the threaded distal portion major diameter less than or equal to the outer diameter **120** of the mid-portion **106** allows the distal threaded portion **104** to pass through a passage in a bone that will be a sliding or press fit with the mid-portion **106**. A screw so configured, as shown in the illustrative example of FIGS. **1-4**, can have an intramedullary canal filling mid-portion **106** providing solid support to a bone interface and a relatively bendable distal threaded portion **104** following a curved path such as for threading into a distal portion of a curved bone to secure the screw in the bone.

The proximal portion **108** may be identical to the mid-portion **106**. Alternatively, the proximal portion may have a positive driver engagement feature (not shown) such as internal or external non-circular surfaces, profiles, or holes. For example, an internal or external slotted, threaded, triangular, square, hexagonal, hexalobular, or other drive feature may be provided. In addition, as shown in the illustrative example of FIGS. **1-4**, the proximal portion **108** may include an optional external helical thread **122** able to engage a bone portion to provide proximal fixation of the screw. For example, the proximal thread **122** may have a major diameter **124**, a minor diameter **126**, and a pitch **130** wherein the proximal thread minor diameter **126** is equal to the mid-portion outer diameter **120**. In the illustrative example of FIGS. **1-4**, the mid-portion outer diameter **120** is equal to the proximal thread minor diameter **126** and the distal thread major diameter **114**. The proximal portion may alternatively, or in addition, receive a locking member such as a pin or screw transverse to the longitudinal axis to lock a proximal bone portion to the nail. The locking member may be drilled through the proximal portion. Preferably, the proximal portion has one or more transverse holes formed through it for receiving the locking member.

The distal and proximal thread pitches **128**, **130** may advantageously be the same or different depending on the application. For example, to stabilize a fracture, the screw **100** may be inserted into a bone across the fracture so that the distal thread **112** is engaged with bone distal to the fracture and the proximal thread **122** is engaged with bone proximal to the fracture. If the bone portions on either side of the fracture are reduced to a desired final position prior to inserting the screw **100**, then it is advantageous for the thread pitches **128**, **130** to be equal so that insertion of the screw does not change the relative positions of the bone portions. If on the other hand, it is desirable to move the bone portions relative to one another by the action of inserting the screw then it is advantageous for the pitches **128**, **130** to be different. For example, to move the bone portions closer together to reduce the fracture, the distal thread pitch **128** may be made greater than the proximal thread pitch **130** so that with the distal thread **112** engaged distally and the proximal thread **122** engaged proximally, further advancing the screw causes the distal bone portion to move proximally relative to the screw faster than the proximal bone portion moves proximally and thus move the bone portions closer together. Alternatively, to move the bone portions further apart to distract the fracture, the distal thread pitch **128** may be made smaller than the proximal thread pitch **130** so that with the distal thread **112** engaged distally and the proximal thread **122** engaged proximally, further advancing the screw causes the distal bone portion to move proximally relative to the screw more slowly than the proximal bone portion moves proximally and thus move the bone portions further apart. Preferably, the bone screw **100** has a through bore, or cannulation **101**, coaxial with the longitudinal axis **110** to permit the bone screw **100** to be inserted over a guide wire.

The bone screw **100** of FIGS. **1-4**, may advantageously be provided in a set containing a plurality of bone screws as shown in the illustrative example of FIGS. **5-7**. For example, it is advantageous in a surgical procedure to minimize the number of steps and the amount of time needed to complete the procedure. In a bone fixation procedure, a surgeon often makes an initial sizing decision based on medical imaging. During the procedure, it may become expedient to change the predetermined size based on observation of the surgical site or the fit of trial implants or instruments. For example, a surgeon may determine initially that a smaller bone screw is appropriate. However, during preparation of the site, the surgeon may determine that a larger screw will better grip the bone or fill, for example, a canal in the bone. The illustrative set of bone screws shown in FIGS. **5-7** facilitates changing between sizes. Each screw **140**, **150**, **160** in the set has a minor diameter **142**, **152**, **162**, a major diameter **144**, **154**, **164**, and a pitch **146**, **156**, **166**. The minor diameters **142**, **152**, **162** are equal to one another so that a single diameter drill will provide an initial bore hole appropriate for all the screws in the set. The pitches **146**, **156**, **166** are equal to one another so that all of the screws in the set will threadably engage a helical thread of the same pitch. The major diameters **144**, **154**, **164** may increase to provide progressively more bone purchase or, for example, to span increasing larger intramedullary canals. For example, with the set of screws of the illustrative example of FIGS. **5-7**, a surgeon may drill a hole equal to the minor diameters **142**, **152**, **162** and then tap the hole with a tap corresponding to the thread of the smallest major diameter screw **140**. The tactile feedback received by the surgeon as the tap is inserted will indicate to the surgeon if the thread major diameter is sufficient to provide a desired level of bone engagement. For example, the surgeon can feel if the tap is engaging the cortical walls of an intramedullary canal or if the tap is in softer cancellous bone. If the surgeon determines that greater engagement is desired, the surgeon can next tap the hole with a tap corresponding to the thread of the next larger major diameter screw **150**. Since the minor diameters **142**, **152**, **162** and thread pitches **146**, **156**, **166** are the same for all of the screws in the set, the next tap will thread into the previously tapped hole and increase the bone thread major diameter without damaging the bone thread. Once the desired bone engagement is achieved, the surgeon may then insert the desired screw **140**, **150**, **160**. If in tapping the larger major diameter thread, the surgeon determines that the bone is providing too much resistance, the surgeon may revert to the smaller sized screw since the threads are still compatible. Alternatively to using a separate tap, the screw threads may be configured as self-tapping so that the screws may be threaded directly into the bored hole.

In addition to the sizing advantages of having the same minor diameter **142**, **152**, **162** across a family of screws, it is also advantageous because the distal threaded portion of each screw will have a similar bending stiffness to each of the other screws **140**, **150**, **160** since the continuous wall of the minor diameter contributes much more to the bending stiffness than the helical thread itself. This similar bending stiffness means that they can be inserted around a similar bending radius with a similar torque.

In the illustrative example of FIGS. **5-7**, each screw **140**, **150**, **160** has a mid-portion diameter **148**, **158**, **168** equal to the corresponding major diameter **144**, **154**, **164**. The increasing mid-portion diameters provide progressively less flexible mid-portions across the set of screws and, for example, canal filling for increasingly larger bones if used in the intramedullary canal. If the screws incorporate the optional increasing mid-portion diameter as shown, then it is desirable to re-drill the mid-portion of the bone hole to accommodate the mid-portion when an increase in screw size is desired. However, the distal, threaded portion of the bone hole does not need to be re-drilled so the screw threads will not be damaged by drilling.

Alternatively to, or in addition to, the threaded distal portion **104** and mid-portion **106** having different sectional moduli, the threaded distal portion **104** and mid-portion **106** may have different material properties such as two different materials or different conditions of the same material to produce a difference in bending stiffness between them.

In the illustrative example of FIGS. **36-41**, a screw **170** has separate first and second members **172**, **174** permanently joined together. The first member **172** includes an elongate body **176** with a proximal end **178**, a distal end **180**, a longitudinal axis **182**, and an axial through bore **184**. The proximal end **178** of the first member includes a pair of transverse through bores **181**, **183**. Each transverse bore **181**, **183** defines a longitudinal axis and the axes form an angle **185** between them about the longitudinal axis **182** as best seen in FIG. **39**. Providing more than one transverse through bore increases options for attaching the screw to bone fragments and options for fixation direction. Both bores may be used for fixation or the one that is most conveniently located. Preferably the angle **185** is in the range of 0 to 90 degrees. More preferably the angle **185** is in the range of 20 to 90 degrees. In the illustrative example of FIGS. **36-41**, the angle **185** is 45 degrees. The proximal end **178** also includes opposed flats **187** for engaging a driver in torque transmitting relationship. An internal thread **189** within the bore **184** is engageable with, e.g., a threaded draw bar to secure the first member to a driver.

The second member **174** includes an elongate body **186** with a proximal end **188**, a distal end **190**, a longitudinal axis **192**, an external helical thread **194**, and an axial through bore **196**. The distal end **180** of the first member **172** and the proximal end **188** of the second member **174** may have complementary geometries to aid in joining them. In the illustrative example of FIGS. **36-41**, the distal end **180** of the first member has a stepped conical taper and the proximal end **188** of the second member has a corresponding stepped conical socket **198**. The mating surfaces may be any suitable shape as determined by the materials and joining technique including but not limited to plug and socket joints (as shown), scarf joints, butt joints, dovetail joints, finger joints, and lap joints. The joint may be reinforced with a third component such as an adhesive, pin, or key. The joint may be formed by mechanical interlock, chemical bonding, molding, welding or other suitable joining process. The final assembled screw **170**, has a distal portion **191**, a mid-portion **193**, and a proximal portion **195** and may have the thread forms, diameters, and relationships as described relative to the examples of FIGS. **1-7**.

The first and second components **172**, **174** may be made of different materials or different conditions of the same material. For example, they may be made of polymers, metals, or ceramics. Metals may include stainless steel alloys, titanium, titanium alloys, cobalt-chromium steel alloys, nickel-titanium alloys, and/or others. Polymers may include nonresorbable polymers including polyolefins, polyesters, polyimides, polyamides, polyacrylates, poly(ketones), fluropolymers, siloxane based polymers, and/or others. Polymers may include resorbable polymers including polyesters (e.g. lactide and glycolide), polyanhydrides, poly (aminoacid) polymers (e.g. tyrosine based polymers), and/or others. Other possible materials include nonresorbable and resorbable ceramics (e.g. hydroxyapatite and calcium sulfate) or biocompatible glasses. They may be made of homogenous materials or reinforced materials. They may be made of crystallographically different materials such as annealed versus cold worked. It is preferable for the mid portion **193** to have a higher bending stiffness than the distal portion **191** and the distal portion should have a bending stiffness low enough for it to be inserted along a curved path in bone.

In a first example, the first component may be made of a metal with a relatively high degree of cold work and the second component of a metal with a relatively low amount of cold work such as for example annealed and cold worked stainless steel. The components may be joined for example by welding. However, as discussed relative to Table 1, most metals are far too stiff to allow threading along a curved path in a bone within suitable torsional loads.

Preferably the distal portion is made of a polymer. In a second example, the first component is made of a metal, such as stainless steel or a titanium alloy, and the second component is made of a polymer such as polyetheretherketone (PEEK) or a polylactide polymer (e.g. PLLA). The components may be joined such as for example by threading them together.

Preferably both components are made of polymers. In a third example, the first and second components are both made of non-resorbable polymers. For example, the first component may be made of fiber reinforced PEEK (e.g. Invibio PEEK-Optima™ Ultra-Reinforced) and the second component may be made of neat (unreinforced) PEEK (e.g. Invibio PEEK-Optima™ Natural). The fiber reinforced PEEK is strong while the neat PEEK is relatively flexible allowing it to be easily threaded around a curved path even while having a relatively large bone filling diameter. The components may be joined, e.g. by molding the components as a continuous matrix with first component fiber reinforcement and second component neat polymer with polymer chains extending across the joint interface. In the example of FIGS. **36-41**, the second component is relatively more transparent to laser radiation than the first component and the parts are joined by laser welding at the conical interface. The laser energy passes relatively easily through the second component and is absorbed by the first component so that localized heating at the conical interface takes place causing the polymer constituent of the two components to fuse together.

In a fourth example, the mid-portion and distal portion are made of resorbable polymers. For example, the mid-portion may be made of a glass fiber reinforced PLLA (e.g. Corbion-Purac FiberLive™) and the distal portion may be made of neat PLLA.

Alternatively, the first member **172** and second member **174** may form one continuous part with different properties between first and second portions. The difference in properties may be achieved, for example, by different processing (e.g. thermal processing) or blending materials. For example, different polymers may be combined in a single injection mold cavity and formed together. The polymers may be blended so that there is a transition between them. In another example, stiffening and/or strengthening material, e.g. fibers, whiskers, and/or granules, may be selectively incorporated in, e.g., the first portion.

FIGS. **42** and **43** illustrate an example of a screw **270** similar to that of FIGS. **36-41** except that the first member **272** is not cannulated, the first member **272** extends the full length of the second member **274**, and the transverse holes **281**, **283** are coplanar. The screw **270** may be assembled as with the prior example including by using complimentary screw threads in the proximal region of the second member **274** and mid portion of the first member **272** as indicated by reference number **250**. The screw **270** of the example of FIGS. **42** and **43** may be include any of the materials and features described relative to the prior examples. If, for example, the first member **272** is made of a radiographically more opaque material than the second member **274**, then the first member will provide a radiographic marker over the entire length of the screw **270** that may be radiographically visualized during and after surgery to confirm screw placement. For example, a metal first component and polymer second component would provide for radiographic visualization of the metal first component. It has been found by the present inventors that the bending stiffness of the distal end of the screw is not materially changed by eliminating the axial through bore of the first component and is essentially unchanged when the bending stiffness of a guide wire is accounted for which was optionally used with the previous cannulated screw examples. The guide wire is not necessary inasmuch as the screw **270** will follow a curved hole prepared to receive it. The transverse holes **181**, **183** may be provided in any number or not at all as desired but it has been found that one is sufficient and two provides the user with additional fixation choice.

FIGS. **44** and **45** illustrate a bone implant **400** useful for stabilizing bone fractures according to one example of the invention. The bone implant **400** includes a body **402** defining a longitudinal axis **404** extending between a proximal end **406** and a distal end **408**. The body has an elongate distal portion **410** having an outer surface **412** defining a screw thread **414** having a minor diameter **416** and a major diameter **418**. The body has an elongate proximal portion **430** having a non-threaded outer surface **432**. Passages **434** and **436** are each formed through the proximal portion **430** transverse to the longitudinal axis from a first opening **438**, **440** on the surface of the proximal portion to a second opening **442**, **444** on the surface of the proximal portion. A driver engaging feature is formed at the proximal end for engaging a driver in torque transmitting relationship. The driver engaging feature may be a male feature or a female feature. Preferably it is a polygonal feature engageable with a correspondingly shaped driver. In the example of FIGS. **44** and **45**, the driver engaging feature is a hexagonal socket **446** formed in the proximal end of the implant. The socket **446** includes a threaded recess **448** for threaded engagement with other tools such as a driver retaining draw rod, a cross pinning guide, or the like. The distal portion is responsive to rotation of the implant to thread into a bone and advance the bone implant into the bone. This rotary advancement action is advantageous compared to typical bone nails that are impacted into the bone since the threaded advancement is less stressful to the bone and surrounding tissues. As the distal portion is threaded into the bone, it pulls the proximal portion into the bone. The distal threaded portion is anchored in the bone by the thread **414**. The smooth proximal portion may be positioned to span a fracture so that, for example, no sharp edges are engaged with the fracture and no stress concentrating features that might weaken the implant span the fracture.

In the example of FIGS. **44** and **45**, the proximal portion has a length **450** measured from the free proximal end **406** to the proximal start **452** of the threads of the distal portion. The proximal portion has a maximum diameter. For example for a conical or cylindrical proximal portion the maximum diameter is simply the largest diameter along the proximal portion. For an ovoid proximal portion, the maximum diameter would be the major diameter of the elliptical cross section. For other shapes, such as fluted proximal portions, the maximum diameter is the maximum dimension normal to the longitudinal axis **404** of the proximal portion. The maximum diameter is preferably constant over a portion of the proximal portion length to provide a uniform thickness for spanning a fracture. For example, the maximum diameter is preferably uniform over at least one-fourth of the proximal portion length; more preferably at least one-third; more preferably at least one-half; more preferably more than one-half. In the illustrative example of FIGS. **44** and **45**, the proximal portion has a constant cylindrical diameter over its entire length. The driver engaging feature preferably has a maximum dimension normal to the longitudinal axis that is less than or equal to the maximum diameter of the proximal portion so that, for example, the proximal end of the bone implant may be seated below the bone surface.

The bone implant may be a unitary construct, like shown in the illustrative example of FIGS. **1-4**, in which the proximal and distal portions are formed of one continuous material. Optionally, the proximal and distal portions may be separate components joined together as shown in the example of FIG. **36** and the example of FIG. **42**. In the illustrative example of FIGS. **44** and **45**, the bone implant includes a sleeve **460** surrounding a separate core **462**. The sleeve and core are joined together to form the body. Various methods may be used to join the sleeve and core. For example, they may be threaded, pinned, bonded, welded, or otherwise joined. In the example of FIGS. **44** and **45**, the sleeve is threaded onto the core via an internal thread **464** and corresponding male thread **466** formed on the core. The sleeve is further pinned to the core with a pin **468** pressed through holes **470**, **472** in the sleeve wall and in the core.

As described relative to previous examples, it is desirable for the distal portion to have a lower bending resistance than the proximal portion. In one example, the sleeve is at least partially formed of a polymer and the core is at least partially formed of a metal. In the example of FIGS. **44** and **45**, the sleeve is machined from a polymer and includes the distal screw thread while the core is machined from a metal and includes the proximal portion. In one example, the core is made of a biocompatible titanium alloy and the sleeve is made of a biocompatible polyaryletherketone polymer such as, for example, polyetheretherketone. In another example, the core is made of a suitable biocompatible metal and the sleeve is made of a resorbable polymer so that, over time, the sleeve will resorb in the patient's body and allow gradually increasing motion of the bone and load transfer to the bone to promote healing. The core may extend partway toward the distal end as in the example of FIG. **36**, all the way to the distal end as in the example of FIG. **42**, or it may extend past the distal end as in the example of FIGS. **44** and **45**. With the tip **480** of the core extending beyond the distal end, the tip **480** provides an easier start of the implant into a hole in the bone and, as shown in the example of FIGS. **44** and **45**, the tip **480** provides a smooth bearing surface for following a curved path in a bone.

FIGS. **46** and **47** illustrate a bone implant **500** similar to that of FIGS. **44** and **45**. The bone implant **500** includes a core **502** and a sleeve **504**. In the example of FIGS. **44** and **45**, the smooth proximal portion **506** is more evenly proportioned over the core and sleeve. Also, the core steps up more gradually in diameter from the distal end **508** to the proximal end **510** resulting in a more gradual transition in bending stiffness over three zones. In a first zone **512**, a relatively thin portion of the core is surrounded by a relatively thick portion of the sleeve. In a second zone **514**, a relatively thicker portion of the core is surrounded by a relatively thinner portion of the sleeve. In a third zone **516**, only a relatively thicker portion of the core remains. Also, in the example of FIGS. **46** and **47** a slip resisting feature is provided on the core and a polymer sleeve is molded to the core so that the polymer and slip resisting feature interdigitate. The slip resisting feature may be knurling, threads, grooves, splines, spikes, holes, or other features. The slip resisting feature may be oriented to enhance torque transfer, longitudinal force transfer, or otherwise oriented. In the example of FIGS. **46** and **47**, the slip resisting feature includes longitudinal splines **518** to enhance the ability to transfer torque between the core and sleeve. Longitudinal force transfer is sufficiently accommodated by the bonding of the sleeve to the core during the molding process.

In use, the preceding implants may be provided in an appropriate size and inserted into a bone to span a fracture in the bone. Preferably the proximal portion of the implant spans the fracture. The arrangement of a smooth proximal portion and a threaded distal portion permits rotating the bone implant to cause the threaded distal portion to engage the bone and pull the proximal portion of the bone implant into a positioning spanning the fracture. In the case of an implant comprising a resorbable polymer, the polymer will resorb over time in the patient to gradually transfer load to and permit motion of the bone to enhance healing of the fracture. One or more pins or screws may be inserted so that they extend through one or more of the passages in the proximal end, for example the proximal passages **434**, **436** in the example of FIGS. **44-45**, and through a portion of the bone to fix the bone to the proximal portion of the implant. For example with the distal end of the bone implant fixed by engagement of the threads in a distal portion of the bone a proximal portion of the bone may be secured with pins or screws as described. This may be used to hold compression or distraction on bone portions on opposing sides of the fracture or to attach loose bone fragments.

FIGS. **8-10** illustrate an implant being inserted into first and second bone portions **200**, **202** having a bone interface **204** between them. The implant could be any of the examples of FIGS. **1**, **36**, **42**, **44**, and **46** and the variations described herein. In the particular example of FIGS. **8-10**, bone screw **100** is shown. A first or proximal bore **206** is formed in the first bone portion **200**, across the bone interface **204**, and into the second bone portion **202**. A second or distal bore **208** extends distally from the proximal bore **206** defining a curved path **210**. The screw **100** is advanced through the proximal bore **206** until the distal screw threads engage the distal bore **208** as shown in FIG. **9**. Further advancing the screw **100** causes it to bend to follow the curved path **210** as shown in FIG. **10**. Having a straight portion of the path, and thus the straight mid portion of the screw **100**, spanning the bone interface results in a zero stress and strain state at the bone interface which prevents separation of the bone portions **200**, **202** at the interface **204**.

FIGS. **11-35** depict an illustrative method of using an implant to fix a fractured clavicle. The implant could be any of the examples of FIGS. **1**, **36**, **42**, **44**, and **46** and the variations described herein. In the particular example of FIGS. **11-35**, bone screw **100** is shown. A patient is placed in a beach chair position with the head rotated away from the operative side. A bolster is placed between the shoulder blades and head allowing the injured shoulder girdle to retract posteriorly. A C-arm is positioned to enable anterior-posterior (AP) and cephalic views of the operative site. A 2-3 cm incision **300** is made at the fracture site along Langer's Lines running perpendicular to the long axis of the clavicle to expose the fracture site (FIG. **10**). The platysma muscle is freed from the skin and split between its fibers. The middle branch of the supraclavicular nerve is identified and retracted.

The medial end **302** of the lateral fragment **304** of the fractured clavicle is elevated from the fracture site incision (FIG. **12**).

A K-wire **306**, e.g. a 1.4 mm K-wire, is drilled into the canal of the lateral fragment **304** and advanced through the dorsolateral cortex **308** and out through the skin (FIG. **13**).

A wire driver is attached to the lateral portion of the K-wire and used to back the wire out until it is lateral to the fracture **310** (FIG. **14**). Bone clamps are used at the incision site to reduce the fracture and clamp the bone fragments in position. Proper reduction is confirmed with AP and cephalic radiographic views.

The K-wire **306** is advanced until it is preferably at least 20 mm medial to the fracture (FIG. **15**).

A first dilator **312**, e.g. a 3.2 mm dilator, is placed over the K-wire and advanced until it contacts the bone (FIGS. **16-17**).

A second dilator **314**, e.g. a 4.5 mm dilator, is placed over the first dilator **312** and advanced until it contacts the bone (FIG. **18**).

A drill guide **316** is placed over the second dilator **314** and advanced until it contacts the bone (FIG. **19**).

The first dilator **312** is removed and a first lateral drill **318**, corresponding to the minor diameter of the distal screw threads, e.g. a 3.2 mm drill, is advanced over the K-wire into the bone, preferably at least 20 mm medial to the fracture. A drill depth mark readable adjacent the drill guide may be noted as a reference for implant sizing (FIG. **20**).

The K-wire is removed and replaced with a flexible guide wire **320**, e.g. a nitinol guide wire, sized to fit within the screw cannulation, e.g. a 1.4 mm guide wire. The flexible guide wire **320** is advanced through the first lateral drill and further along the intramedullary canal of the medial bone fragment and will curve to follow the intramedullary canal to define a curved path in the bone. Preferably, the guide wire is advanced approximately 30 mm medial to the tip of the first lateral drill **318** (FIG. **21**).

The first lateral drill **318** is removed and a flexible shaft reamer **322**, corresponding to the minor diameter of the distal screw threads, is guided over the flexible guide wire **320** to ream the medial portion of the curved path (FIG. **22**) The flexible reamer **322** and second dilator **314** are then removed.

A second lateral drill **324**, having a diameter corresponding to the diameter of the mid-portion of the screw, e.g. a 4.5 mm drill, is guided over the flexible guide wire to enlarge the bone hole laterally to receive the mid-portion and proximal portion of the screw **100**. The second lateral drill **324** is advanced the same distance as the first lateral drill (FIG. **23**). The drilling step may be monitored in A/P and cephalic views with the C-arm to avoid perforating the bone cortex as the second lateral drill **324** is advanced into the medial bone fragment **326**.

A flexible tap **328**, having cutting threads corresponding to the distal threads of the screw **100** is guided over the flexible guide wire to cut threads into the medial bone fragment along the curved path (FIG. **24**). The tap may serve as a trial implant and provides tactile feedback regarding the fit of the implant in the bone. If it is determined that a larger screw is desirable, subsequent larger second drills may be used to re-drill the lateral straight portion and subsequent larger flexible taps may be used to increase the distal thread major diameter without having to re-ream the medial curved portion of the bone hole. Once a desired level of thread purchase and canal filling are achieved, a depth mark readable adjacent the drill guide may be noted as a reference for the required implant length. If a screw **100** with a proximal threaded portion is used, a lateral tap may be used to tap the lateral bone fragment to receive the proximal threads.

The screw **100** is attached to an inserter **330** and guided over the flexible guide wire until it is fully seated in the prepared threads in the medial bone fragment (FIGS. **25** and

26). Optionally, the screw **100** may be axially driven with a mallet through the lateral bone fragment until just short of the distal thread engagement. The screw **100** may then be threaded into full engagement with the prepared threads in the medial fragment. Radiographic visualization may be used to ensure that the fracture is fully reduced and anatomically aligned in length and rotation.

If a proximally threaded screw has not been used, or if additional fixation is otherwise desired, cross fixation may be used. For example, a cross fixation guide **340** may be engaged with the implant inserter **330** (FIG. **27**). The cross fixation guide may include a knob **342** that threadingly engages the implant inserter **330** and a cross fixation guide sleeve **344** that abuts the lateral bone fragment adjacent the bone hole entrance. Rotating the knob **342** moves the cross fixation guide sleeve **344** and implant inserter **330** axially relative to one another. With the cross fixation guide sleeve **344** abutting the lateral bone fragment **304**, the implant inserter, implant, and medial bone fragment **326** will be drawn laterally and the lateral bone fragment **304** will be pressed medially to apply compression across the fracture.

Inner and outer drill sleeves **346**, **348** are advanced through the guide **340** until they abut the bone (FIG. **28**). In the case of a screw such as the examples of FIGS. **36**, **42**, **44** and **46** having one or more preformed transverse bores, the cross fixation guide may have one or more targeting holes positioned to align with the one or more transverse bores. In the case of a screw such as the example of FIG. **1** not having preformed transverse bores, cross fixation may be inserted directly through the screw **100** forming a transverse bore intraoperatively.

For example, a cross fixation wire **350** may be guided through the drill sleeves, through the near cortex, through the mid or proximal portions of the screw, and into the far cortex of the lateral bone fragment (FIG. **29**). If wire cross fixation is adequate, the cross fixation guide may be removed and the wire may be trimmed flush with the bone surface.

However, if screw cross fixation is desired, a screw depth gauge **352** may be placed over the cross fixation wire to measure the projecting portion of the guide wire to determine the required screw length for bi-cortical fixation (FIG. **30**).

A countersink tool **354** may be used to create a countersink for a cross fixation bone screw **356** (FIG. **31**).

The appropriate length cross fixation screw **356** may then be guided over the cross fixation wire **350** and seated into the bone (FIG. **32**). These steps may be repeated to place additional screws if desired.

FIGS. **33** and **34** illustrate the location of the screw **100** and cross fixation screws **356** relative to the lateral and medial bone fragments.

FIG. **35** illustrates the cross fixation screws **356** in the screw **100** without the bone to obscure the view. Preferably the screw **100** is made of a relatively soft material, e.g. a polymer, that facilitates arbitrary placement of the cross fixation screws at any desired location.

Various examples have been presented to aid in illustrating the invention. These various examples are illustrative but not comprehensive and variations may be made within the scope of the invention. For example, the various features described relative to each example may be interchanged among the examples.

What is claimed is:

1. A bone screw for stabilizing bone fractures, the bone screw comprising:

a body defining a longitudinal axis extending between a proximal end and a distal end;

an elongate proximal portion of the body comprising a first material; and

an elongate distal portion of the body comprising a second material different from the first material such that a material composition of the body varies along a length of the body, the elongate distal portion having an outer surface defining a helical distal screw thread formed on a threaded distal portion, wherein the threaded distal portion is formed entirely of the second material, the helical distal screw thread having a minor diameter and a major diameter, wherein the second material has a lower stiffness than the first material, and

wherein a part of the body that is proximal to the helical distal screw thread has a diameter that is greater than the minor diameter of the helical distal screw thread.

2. The bone screw of claim **1** further comprising a passage formed through the elongate proximal portion transverse to the longitudinal axis from a first opening on an outer surface of the elongate proximal portion to a second opening on the outer surface of the elongate proximal portion.

3. The bone screw of claim **1** wherein the body comprises a sleeve surrounding a separate core, the sleeve and core being joined together to form the body.

4. The bone screw of claim **3** wherein the helical distal screw thread is formed on the sleeve.

5. The bone screw of claim **4** wherein the elongate proximal portion comprises the core extending proximally from the sleeve.

6. The bone screw of claim **4** wherein the sleeve comprises a polymeric material, the helical distal screw thread being formed in the polymeric material of the helical distal screw thread.

7. The bone screw of claim **6** wherein the core comprises a metal.

8. The bone screw of claim **6** wherein the sleeve comprises a resorbable polymer.

9. The bone screw of claim **8** wherein the core comprises a reinforced polymer.

10. The bone screw of claim **6** wherein the core comprises a slip resisting feature formed on a surface of the core and the sleeve is molded onto the core so that the polymeric material and slip resisting feature interdigitate.

11. The bone screw of claim **6** wherein the polymeric material comprises polyetheretherketone and the core comprises titanium.

12. The bone screw of claim **3** wherein the sleeve is pinned to the core.

13. The bone screw of claim **3** wherein the sleeve is threaded onto the core.

14. A bone screw for stabilizing bone fractures, the bone screw comprising:

a body defining a longitudinal axis extending between a proximal end and a distal end;

an elongate proximal portion of the body comprising a first material; and

an elongate distal portion of the body comprising a second material such that the elongate distal portion of the body has a second bending stiffness less than half of a first bending stiffness of the elongate proximal portion, the elongate distal portion having an outer surface defining a helical distal screw thread formed on a threaded distal portion, wherein the threaded distal portion is formed entirely of the second material, the helical distal screw thread having a minor diameter and a major diameter, and wherein the helical distal screw thread has a length, along the longitudinal axis, at least twice its minor diameter.

15. The bone screw of claim **14** further comprising a passage formed through the elongate proximal portion transverse to the longitudinal axis from a first opening on an outer surface of the elongate proximal portion to a second opening on the outer surface of the elongate proximal portion.

16. The bone screw of claim **14** wherein the body comprises a sleeve surrounding a separate core, the sleeve and core being joined together to form the body.

17. The bone screw of claim **16**, wherein

the core is formed of the first material;

the sleeve is formed of the second material;

the first material comprises titanium; and

the second material comprises polyetheretherketone.

18. The bone screw of claim **17**, wherein the sleeve is secured to the core via at least one selection from the group consisting of:

a pin passing through aligned holes in the sleeve and the core; and

sleeve threads of the sleeve that engage core threads of the core.

19. A bone screw for stabilizing bone fractures, the bone screw comprising:

a body defining a longitudinal axis extending between a proximal end and a distal end;

an elongate proximal portion of the body comprising a first material comprising a metal; and

an elongate distal portion of the body comprising a second material comprising a polymer, the elongate distal portion having an outer surface defining a helical distal screw thread formed on a threaded distal portion, wherein the threaded distal portion is formed entirely of the second material, the helical distal screw thread having a minor diameter and a major diameter;

wherein the first material is not present in the elongate distal portion, or is present in the elongate distal portion with a second thickness, perpendicular to the longitudinal axis, that is less than a first thickness, perpendicular to the longitudinal axis, of the first material within the elongate proximal portion, and

wherein a part of the body that is proximal to the helical distal screw thread has a diameter that is greater than the minor diameter of the helical distal screw thread.

20. The bone screw of claim **19** wherein:

the body comprises a sleeve surrounding a separate core, the sleeve and core being joined together to form the body;

the core is formed of the first material;

the sleeve is formed of the second material;

the helical distal screw thread is formed on the sleeve; and

the elongate proximal portion comprises the core extending proximally from the sleeve.

21. A bone screw for stabilizing bone fractures, the bone screw consisting essentially of:

a body defining a longitudinal axis extending between an elongate proximal portion and an elongate distal portion, the body comprising:

a core, formed of a metal, extending at least through the elongate proximal portion; and

a sleeve, formed of a polymer, surrounding and immovably joined to the core and extending through the elongate proximal portion and the elongate distal portion;

wherein:

the elongate distal portion comprises an outer surface defining a helical distal screw thread; and

the elongate distal portion is sufficiently flexible to bend in response to insertion of the distal end into a curved portion of a hole in human bone.

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